

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE ACTIQ SALES AND MARKETING
PRACTICES LITIGATION**

Civil Action No. 07-CV-04492 (PBT)

Honorable Petrese B. Tucker

**MEMORANDUM OF LAW
IN OPPOSITION TO PLAINTIFFS' MOTION
FOR CLASS CERTIFICATION**

**(Filed Under Seal Pursuant to the Amended Stipulation and Protective Order
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I. INTRODUCTION

After years of discovery and motion practice, Plaintiffs have abandoned the consumer fraud claims that comprised the core of their complaint. They now seek to certify a nationwide class solely under an unjust enrichment theory and to divest Cephalon of its profits from off-label prescriptions of Actiq, a pain management medicine that Plaintiffs concede is effective and that provided many patients and their insurers with a considerable benefit. The proposed class consists of every third-party payor (“TPP”) in the United States that paid for off-label prescriptions of Actiq over a five-year period. Class members in this case are not consumers, but a variety of insurance entities suing for alleged economic loss.

There are numerous independent reasons why such a class should not be certified. However, an overarching reason why the proposed class must fail is because, under Plaintiffs’ theory, they must show that Cephalon was “unjustly” enriched at each putative class member’s expense. The only way to properly make such a determination is to consider the individual circumstances of each doctor’s prescribing decision and each TPP’s reimbursement decision, including what, if anything, Cephalon did to influence those decisions. Moreover, determining liability will depend on whether individual insureds received a benefit from Actiq and whether the TPP avoided more expensive treatment alternatives as a result of the Actiq prescriptions. What may be “unjust” for one class member may not be so for another, as the factual circumstances and applicable law will vary. In short, Plaintiffs cannot prove their equitable theory on a classwide basis because:

- Cephalon did not engage in uniform conduct towards each doctor and each TPP;
- Doctors prescribed Actiq for many different reasons, and many were not either exposed to, or influenced by, anything that Cephalon did or said;
- Many off-label prescriptions of Actiq were medically appropriate, because they provided a significant therapeutic benefit to patients by alleviating their breakthrough pain;

- TPPs chose to adopt or not adopt varying limitations regarding reimbursement of Actiq for independent business reasons and motivations specific to each TPP;
- Many TPPs chose to pay for off-label prescriptions of Actiq with full knowledge that they were doing so and after expressly approving each prescription;
- Many TPPs suffered no injury, and indeed may have avoided significant expense for alternative treatments, as a result of off-label prescriptions of Actiq; and
- Many TPPs were able to recoup their costs through increased premiums.

Because there is no common, class-wide evidence that is capable of resolving all unjust enrichment claims by all putative class members in “one stroke,” *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2551 (2011), the individualized circumstances behind each prescription—each doctor’s prescribing decision, the benefit of Actiq to each patient, the benefit received by each TPP, and each TPP’s reimbursing decision—would need to be separately analyzed to determine whether it would be “unjust” or “inequitable” for Cephalon to retain the profits from that prescription.

Plaintiffs’ attempt to use the Actiq Risk Management Program (“RMP”) cannot and does not change the need for such individualized inquiries. The RMP plainly does not support what Plaintiffs argue—that all off-label prescriptions exceeding 15% of all Actiq prescriptions were medically unnecessary. First, the RMP does not address whether off-label prescriptions are medically necessary. Indeed, both the Supreme Court and FDA have recognized that the FDA does not limit the practice of medicine or prescribing decisions by doctors. At most, the RMP can be read to suggest that the FDA wanted to ensure that doctors who prescribed off-label did so with knowledge of Actiq’s approved indication and risks. Second, the 15% threshold in the RMP was a trigger for Cephalon to provide further educational materials to certain prescribing doctors; it was by no means a ceiling on appropriate off-label usage. Third, Plaintiffs’ own experts concede that the FDA’s 15% threshold was arbitrary; no empirical analysis was conducted to determine what an acceptable level of medically-appropriate off-label prescriptions would be. Finally, even assuming that Cephalon failed to provide the education required by the RMP, there is no common basis to

assume that doctors would have ceased prescribing Actiq had they received reminders with respect to its approved labeling and risks, and the evidence of record is to the contrary.

Both the Supreme Court and the Third Circuit have recognized that Plaintiffs bear the burden of presenting evidence to satisfy each element of Rule 23(a) and Rule 23(b)(3), including the “‘capacity of a class[-]wide proceeding to generate common *answers* apt to drive the resolution of the litigation.’” *Dukes*, 131 S. Ct. at 2551 (emphasis in original) (quotations omitted); *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 318, 320 (3d Cir. 2009). Plaintiffs have not and cannot satisfy their burden for multiple independent reasons.

As a threshold matter, numerous courts have denied class certification for claims brought by TPPs against pharmaceutical companies based upon allegations of off-label promotion—the very theory that Plaintiffs rely upon here.¹ These cases recognize that because both prescribing doctors and reimbursing TPPs must exercise their independent judgment before any prescription is written and paid for, there is simply no way to prove these kinds of claims on a class-wide basis. Those reasons are even more significant in the unjust enrichment context, which requires the Court to make equitable determinations after considering the facts and circumstances in each instance. Given the many particularized circumstances that must be considered as to each prescription and each reimbursement determination by each TPP, individual issues clearly will predominate over any questions of law and fact that are common to the putative class.

Second, Plaintiffs’ proposed nationwide and alternative multi-state classes fail because they are unmanageable due to the many variations in applicable law. Under Pennsylvania choice-of-law principles, the Court must conduct an analysis of the potentially competing unjust enrichment laws,

¹ See, e.g., *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 136 (2d. Cir. 2010); *Sergeants Benevolent Assoc. Health & Welfare Benefit Fund v. Sanofi-Aventis U.S. LLP*, No. 08-cv-0179, 2011 WL 824607, at *14-15 (E.D.N.Y. Feb. 16, 2011); *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 257 F.R.D. 315, 324-27 (D. Mass. 2009); *Wyeth, Inc. v. Blue Cross and Blue Shield of Ala.*, 42 So. 3d 1216, 1226-27 (Ala. 2010); *Int’l Union of Operating Eng’rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1087-88 (N.J. 2007).

which, in this case, requires consideration of the laws of all 51 jurisdictions. That analysis alone makes this case unmanageable as a class action. Moreover, these laws differ in many material ways. Compounding the complexity, because the law of unjust enrichment is undeveloped in many jurisdictions, the Court would need to make numerous guesses as to the unjust enrichments laws of each jurisdiction to determine whether, ultimately, the Court would need to apply the materially different laws of multiple jurisdictions. Because different legal standards will apply to different claims by different TPPs, any class trial would be hopelessly complex and unmanageable.

Third, while Cephalon does not challenge the adequacy of Plaintiffs' counsel, Plaintiffs themselves are not adequate class representatives. Despite pleading statutory consumer fraud claims, which, for many states, allow class members to receive actual damages, have a longer statute of limitations period, and permit the award of attorneys' fees, Plaintiffs have abandoned those claims. As a result, Plaintiffs have acted to the detriment of the proposed class.

Fourth, based upon the depositions of named Plaintiffs and the doctors who prescribed Actiq to their insureds, it is clear that Plaintiffs' claims are not typical of the claims of other class insureds. Unlike other putative class members, Plaintiffs received no communications from Cephalon, they expressly chose not to implement controls that would have precluded costs for off-label prescriptions of Actiq, each insured of each Plaintiff received a significant therapeutic benefit from Actiq, and each doctor who prescribed Actiq to each of their insureds has testified that he or she was not influenced by anything that Cephalon said or did. These facts not only preclude Plaintiffs' unjust enrichment claims, but make those claims substantially different from those of other class members.

Fifth, a class action is not a superior mechanism because the amount of alleged damages sustained by each TPP is potentially substantial. Each TPP therefore has an incentive to bring its own claims, to the extent it wants to do so.

Finally, Plaintiffs' class definition is fatally overbroad because it includes TPPs who suffered no injury as a result of anything that Cephalon did or said. Pursuant to *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235 (3d Cir. 2012), and well-settled principles of standing under Article III, these TPPs have no standing.

For all of these reasons, Plaintiffs' class certification motion must be denied.

II. BACKGROUND

In their amended complaint, Plaintiffs alleged that Cephalon engaged in a fraudulent and deceptive marketing campaign which, in turn, *caused* doctors to write “medically unnecessary and inappropriate prescriptions” of Actiq when “a wide array of less expensive pain management drugs [that] were [more] appropriate, less dangerous and posed no risk of dangerous opiate addiction” was available. (Am. Compl., attached hereto as Ex. 2, at ¶¶ 1, 5; *see also id.* at ¶ 67 (“physicians prescribed Actiq off-label for unapproved uses *due to the* Company’s relentless off-label promotion through its sales force and its deceptive marketing practices” (emphasis added))). Plaintiffs further alleged that “Cephalon injured third-party payors by *forcing* them to pay for an expensive prescription medication that was medically unnecessary for general pain management” and that “*would not have been prescribed in the absence* of Defendant’s marketing campaign.” (*Id.*, at ¶¶ 61, 75 (emphasis added))). Based upon these allegations, Plaintiffs asserted statutory consumer fraud and unjust enrichment claims on behalf of themselves and a putative nationwide class of all TPPs.² Inherent in these allegations are Plaintiffs’ contentions that doctors would not have written the Actiq prescriptions in the absence of Cephalon’s marketing; that TPPs were all somehow forced to reimburse for Actiq; and that, for all insureds, there was a less expensive and effective alternative medicine that should have been prescribed.

² Plaintiffs also asserted claims under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961 *et seq.*, which have been dismissed with prejudice.

Discovery has shown that none of these propositions can be established on a class-wide basis. Thus, Plaintiffs no longer seek class certification on their statutory consumer fraud claim, are not seeking damages in the amount that each class member actually paid for Actiq, and apparently are no longer pursuing their theory that Cephalon engaged in fraudulent off-label promotion. (Pls. Br. In Support Of Mot. For Class Cert. (“Pls. Br.”), Doc. No. 345, at 2-3 (seeking certification only under “unjust enrichment law”); Pls. Trial Plan, Ex. 191 to Pls. Br., at 1 (same)). Instead, Plaintiffs now purport to proceed solely on their unjust enrichment claim under their newly-articulated theory that Cephalon somehow “conceal[ed]” information from doctors by not disclosing that Actiq “should never be used outside its approved indication” and failed affirmatively to “halt the off-label prescriptions.” (Pl. Br. at 1, 17). Based upon a theory of Cephalon’s alleged “failure to act to prevent non-cancer prescriptions.” (*id.* at 37), Plaintiffs seek disgorgement of Cephalon’s profits with respect to off-label prescriptions of Actiq above a 15% threshold between January 2002 and December 2006 (“Proposed Class Period”).

A. FDA Did Not And Could Not Preclude Doctors From Writing Off-Label Prescriptions Of Actiq.

As explained by Dr. Scott Gottlieb, former FDA Deputy Commissioner for Medical and Scientific Affairs, the FDA does not regulate the practice of medicine.³ As a result, there is a fundamental difference between off-label prescribing and off-label promotion.

“Off-label prescribing” refers to the well-established and entirely proper physician practice of prescribing a medicine for a purpose different from that expressly approved by the FDA.⁴ As Plaintiffs concede, “[d]octors are free to prescribe a drug for a non-approved or ‘off-label’ use.”⁵ Thus, in exercising their independent medical judgment, doctors are free to prescribe a drug—

³ See FDA, *Guidance For Industry - Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 13, 2009), available at <http://www.fda.gov/oc/op/goodreprint.html>, attached as Ex. 122 to March 20, 2013 Declaration of Jeremy Menkowitz (“Menkowitz Decl.”).

⁴ Pls. Am. Compl., attached as Ex. 2 to Menkowitz Decl., at ¶¶ 23, 37.

⁵ *Id.* at ¶ 37.

including Actiq—to treat *any* condition or symptom, regardless of whether the condition or symptom is covered by the FDA-approved labeling.⁶

“Off-label promoting” refers to a pharmaceutical company promoting a medicine for a use not approved by the FDA. Off-label promotion (as opposed to off-label prescribing) is subject to federal regulatory action only by the FDA and enforcement only by the Department of Justice; there is no private cause of action to enforce these regulations.⁷ Not all off-label communications by a pharmaceutical company are unlawful. Truthful off-label promotion is protected by the First Amendment,⁸ and there is nothing intrinsically untruthful about off-label communications.⁹

Off-label prescriptions of approved drugs may be beneficial to a patient. The Supreme Court, the Third Circuit, and the FDA have all recognized that off-label prescriptions may form the proper standard of care for patient treatment.¹⁰ Pain medicine is one such example. As explained

⁶ See Expert Report of Dr. Scott Gottlieb (“Gottlieb Report”), attached as Ex. 26 to Menkowitz Decl., at ¶¶ 14, 23-26; Jan. 17, 2013 Deposition of Professor Meredith Rosenthal (“Rosenthal Dep.”), attached as Ex. 18 to Menkowitz Decl., at 91:14-92:12; Dr. Deborah Leiderman (“Leiderman Dep.”), attached hereto as Ex. 20, at 104:20-105:9.

⁷ See, e.g., *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994) (“violations of the FDCA do not create private rights of action”); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.* (“*In re Epogen I*”), 590 F. Supp. 2d 1282, 1289-90 (C.D. Cal. 2008) (dismissing claims because “allegations of off-label promotion are, in essence, misbranding claims that should be reviewed by the FDA”), *aff’d by*, *United Food & Commercial Workers Cent. Pa. & Reg. Health & Welfare Fund v. Amgen, Inc.*, 400 Fed. Appx. 255, 257 (9th Cir. 2010).

⁸ See, e.g., *United States v. Caronia*, 703 F.3d 149, 168-69 (2d Cir. 2012).

⁹ See, e.g., *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.* (“*In re Epogen II*”), No. 08-1934, 2009 WL 1703285, at *5, 7 (C.D. Cal. June 17, 2009) (“off-label promotion is not inherently fraudulent; truthful off-label promotion of drugs does not violate RICO or state consumer protection laws”) (emphasis in original); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.* (“*In re Epogen I*”), 590 F. Supp. 2d 1282, 1292 (C.D. Cal. 2008); *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1051, 1054-55 (N.D. Cal. 2009) (dismissing plaintiffs’ RICO and consumer fraud claims based upon off-label marketing and sale of prescription medicines because plaintiffs failed to allege “a false and misleading statement about the drug itself” (emphasis in original)); *United States v. Caronia*, 576 F. Supp. 2d 385, 397 (E.D.N.Y. 2008), *vacated and remanded by*, 703 F.3d 149 (2d Cir. 2012) (“Promotion of off-label uses is not inherently misleading simply because the use is off-label.”); *United States ex. rel. Hess v. Sanofi-Synthelabo, Inc.*, No. 4:05CV570MLM, 2006 WL 1064127, at *9-10 (E.D. Mo. Apr. 21, 2006) (despite defendant having engaged in off-label promotion, plaintiff’s allegations fail because “none of the actions which Plaintiff alleges on the part of Defendant . . . involve conduct which was designed to present false information”).

¹⁰ See, e.g., *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 351 n.5 (2001) (recognizing that off-label prescribing and use “often is essential to giving patients optimal medical care”) (internal citations and quotations omitted); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239-40 (3d Cir. 2011) (“Prescription drugs frequently have therapeutic uses other than their FDA-approved indications.”); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 06-5774, 2009 WL 2043604, at *10 (D.N.J. July 10, 2009) (off-label prescribing of prescription medicines “is, often times, the best means for providing effective treatment for patients”); *In re Actimmune*, 614 F. Supp. 2d at 1041 n.1 (“Physicians . . . may lawfully prescribe a drug for ‘off-label’ indications to achieve therapeutic goals other than those for which the drug was approved.”); *Use of Approved Drugs for Unlabeled Indications*, FDA Drug Bulletin, Vol. 12, No. 1, at 4-5 (Apr. 1982) (“accepted medical practice often

by Dr. Michael Ashburn, Chief of the Division of Pain Medicine at the University of Pennsylvania Hospital, doctors often use medications outside their approved indications for the treatment of pain, including pain following trauma or surgery, cancer-related pain, and chronic non-cancer pain.¹¹ Many such products are approved with a limited indication or no pain indication at all, but are often prescribed off-label for patients experiencing a variety of chronic and severe pain.¹²

Actiq is one such medicine. It was approved by the FDA in November 1998 for the “management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”¹³ The active pharmaceutical ingredient in Actiq is fentanyl citrate, an opioid.¹⁴ Plaintiffs have taken the position that fentanyl citrate is so powerful, and thus Actiq is allegedly so dangerous, that it is almost never appropriate to use it for anything except breakthrough cancer pain. (Pls. Br., at 1, 11-12, 34). Yet, products containing fentanyl have been available on the market for decades and have been approved by the FDA for, among other things, use by anesthesiologists in surgical operating rooms.¹⁵ Indeed, prior to the approval of Actiq, the FDA approved a similar “lollipop” formulation containing fentanyl citrate (under the brand name Oralet®) for pre-surgical anesthesia *in children*.¹⁶

includes drug use that is not reflected in approved drug labeling”); FDA, *Guidance For Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 13, 2009), Ex. 122; 63 Fed. Reg. 31143, at 31153 (June 8, 1998).

¹¹ See Expert Report Of Dr. Michael Ashburn (“Ashburn Report”), attached as Ex. 22, at ¶¶ 32-33, 39.

¹² In fact, the Federation of State Medical Boards of the United States has published a model policy (“Model Policy”) for the prescribing of controlled substances, such as opioids, for the treatment of pain. See, e.g., Model Policy, attached as Ex. 58. Several states have adopted this policy in varying forms. See, e.g., Virginia Policy On Opioid Prescribing, attached as Ex. 59 to Menkowitz Decl.; California Policy On Opioid Prescribing, attached as Ex. 60 to Menkowitz Decl. This model policy recognizes, among other things, that “controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins.” Ex. 58, at Section 1, p. 3. This policy does not limit the appropriate prescribing of opioids for pain to on-label conditions.

¹³ See ACTIQ Label, attached as Exhibit 27 to Menkowitz Decl.

¹⁴ Ashburn Rep., Ex. 22, at ¶ 20.

¹⁵ Ashburn Rep., Ex. 22, at ¶ 21.

¹⁶ Ashburn Rep., Ex. 22, at ¶ 22.

As Plaintiffs concede, Actiq is an effective pain medicine. (Pls. Br. 34). Actiq can be absorbed through the blood vessels in the patient's gums, thus providing rapid pain relief while delivering a comparably small dosage of fentanyl.¹⁷ Because of its ability to provide fast pain relief, it can be an effective alternative to the treatment of breakthrough pain regardless of whether that pain is caused by cancer or some other source.¹⁸ And, as described in more detail below, Actiq provided significant and important pain relief to the named Plaintiffs' insureds.

Actiq was approved by the FDA subject to a Risk Management Program ("RMP").¹⁹ As Dr. Gottlieb explains, the Actiq RMP was not intended to preclude off-label prescribing.²⁰ Instead, it was designed, in part, to communicate the characteristics of Actiq to medical doctors so that they were aware of Actiq's indication and risk profile when deciding whether to prescribe it.²¹ As explained in the introductory paragraph of the RMP, one of the risks that it was meant to address was "inappropriate patient selection," which is defined as prescribing to a patient who was not already "opioid tolerant."²² That concern had nothing to do with whether the patient had cancer, and Plaintiffs' expert has conceded that non-cancer patients may also meet the definition of "opioid tolerant" as a result of using long-acting opioids for their conditions.²³

Because it was possible that doctors who prescribed Actiq off-label were not attuned to its approved indication and risks, the RMP required the drug's "sponsor" (first Abbott, and later Cephalon) to engage in certain educational follow-up with particular individual doctors and groups of doctors in certain specified circumstances:

¹⁷ Ashburn Rep., Ex. 22, at ¶ 22.

¹⁸ Ashburn Rep., Ex. 22, at ¶¶ 38-42.

¹⁹ Actiq was developed by Anesta Corp. in collaboration with Abbott Laboratories. It was approved by the FDA in November 1998. Cephalon acquired the rights to Actiq in July 2000, when it merged with Anesta. *See Cephalon and Anesta Announce Merger to Create Stronger, More Profitable Pharmaceutical Business* (July 17, 2000), available at http://investors.cephalon.com/phoenix.zhtml?c=81709&p=irol-newsArticle_print&ID=182729&highlight=.

²⁰ Gottlieb Rep., Ex. 26, at ¶¶ 18, 45.

²¹ *Id.* at ¶¶ 48-49.

²² Actiq RMP, attached as Ex. 41 to Menkowitz Decl., at § 1.0; Gottlieb Rep., Ex. 26, at ¶ 49.

²³ Leiderman Dep., Ex. 20, at 188:14-22; Gottlieb Rep., Ex. 26, at ¶¶ 44-45.

- **Individual Prescribers.** Pursuant to Section 9.1.1 of the RMP, “[w]henver a problem of off-label usage becomes known and individual prescribers are identified,” the sponsor was required: (a) to send a letter to the prescriber identifying “the approved indication”; and (b) if a problem persists, to have a specialist “visit the physician/s to gather information and remind them of appropriate prescribing of *Actiq*.”²⁴
- **Group Prescribers.** Pursuant to Section 9.1.2 of the RMP, if “groups of physicians (such as a particular specialty) are identified as having prescribed *Actiq* inappropriately, and these prescriptions represent potential off-label usage greater than 15% of total quarterly *Actiq* prescriptions,” then the sponsor was required to: (a) send a letter to the appropriate professional society to “outline prescribing concerns and offer to implement an educational program”; and (b) if levels did not decrease below 15% for 2 additional quarters, “initiate an aggressive educational program” warning of potential liabilities of prescribing *Actiq*.²⁵

These requirements were not applicable to all prescribers and, as Dr. Gottlieb explains, these provisions do not make any assumptions about what caused a doctor to prescribe off-label, nor do they make any reference to off-label promotion.²⁶ The RMP also does not provide any explanation as to how the FDA arrived at the 15% trigger for following up with particular prescribers in Section 9.1.2.²⁷

B. Doctors Wrote Prescriptions Of Actiq Based Upon Individualized Considerations And There Is No Common Evidence Of Conduct By Cephalon That Influenced Each Prescription At Issue.

It is difficult to imagine a more fact-specific and individualized decision than a doctor’s exercise of medical judgment in determining how to treat a patient suffering from debilitating pain. As explained by Dr. Ashburn, doctors write prescriptions for many different reasons.²⁸ Each prescription is an individualized decision, based upon individualized criteria. The factors that influence a doctor’s medical judgment include his or her medical training and experience generally; specific experience with *Actiq* and/or its active ingredient in the past; exposure to and understanding of the scientific literature regarding *Actiq* and similar drugs; the experiences of, and

²⁴ Actiq RMP, Ex. 41, at ¶ 9.1.1.

²⁵ Actiq RMP, Ex. 41, at ¶ 9.1.2.

²⁶ Gottlieb Rep., Ex. 26, at ¶¶ 48, 51.

²⁷ Gottlieb Rep., Ex. 26, at ¶¶ 50-51; Leiderman Dep., Ex. 20, at 269:18-270:12.

²⁸ Ashburn Rep., Ex. 22, at ¶¶ 29, 32.

discussions with, the doctor's peers; the treatment history of the patient, including whether the patient has tried and failed alternative therapies, or whether the patient has had past success with Actiq and is seeking a refill; the doctor's individual assessment of the benefits of Actiq versus the risks of taking it; the patient's personal desire for pain relief and risk tolerance; and influence by third party payers such as insurance companies.²⁹ These factors are valued differently by different doctors and for different patients.³⁰ They also change over time.³¹

Pharmaceutical promotion is just one factor that may affect a doctor's treatment choice. As confirmed by Professor Chintagunta, the Joseph T. and Bernice S. Lewis Distinguished Service Professor of Marketing at the Graduate School of Business for the University of Chicago, academic research demonstrates that the effect of promotion on doctors' prescribing decisions is highly dependent on the doctor and other factors.³² Each doctor responds differently. Some doctors even respond negatively to detailing, and some do not respond at all.³³

²⁹ Ashburn Rep., Ex. 22, at ¶ 36. [REDACTED]

[REDACTED] See also Cephalon's Statement of Material Facts ("SOF"), attached as Ex. 1 to Menkowitz Decl., at ¶ 118.

³⁰ Ashburn Rep., Ex. 22, at ¶¶ 36-37. Plaintiffs acknowledged that many of these factors affect a doctor's choice of which drug to prescribe. See Rosenthal Dep., Ex. 18, at 115:23-116:3, 119:13-25.

³¹ Ashburn Rep., Ex. 22, at ¶ 36.

³² Report of Professor Pradeep Chintagunta ("Chintagunta Report"), attached as Ex. 24 to Menkowitz Decl., at ¶¶ 77-81, 84; Rosenthal Dep., Ex. 18, at 111:8-14, 112:5-13, 113:23-114:4.

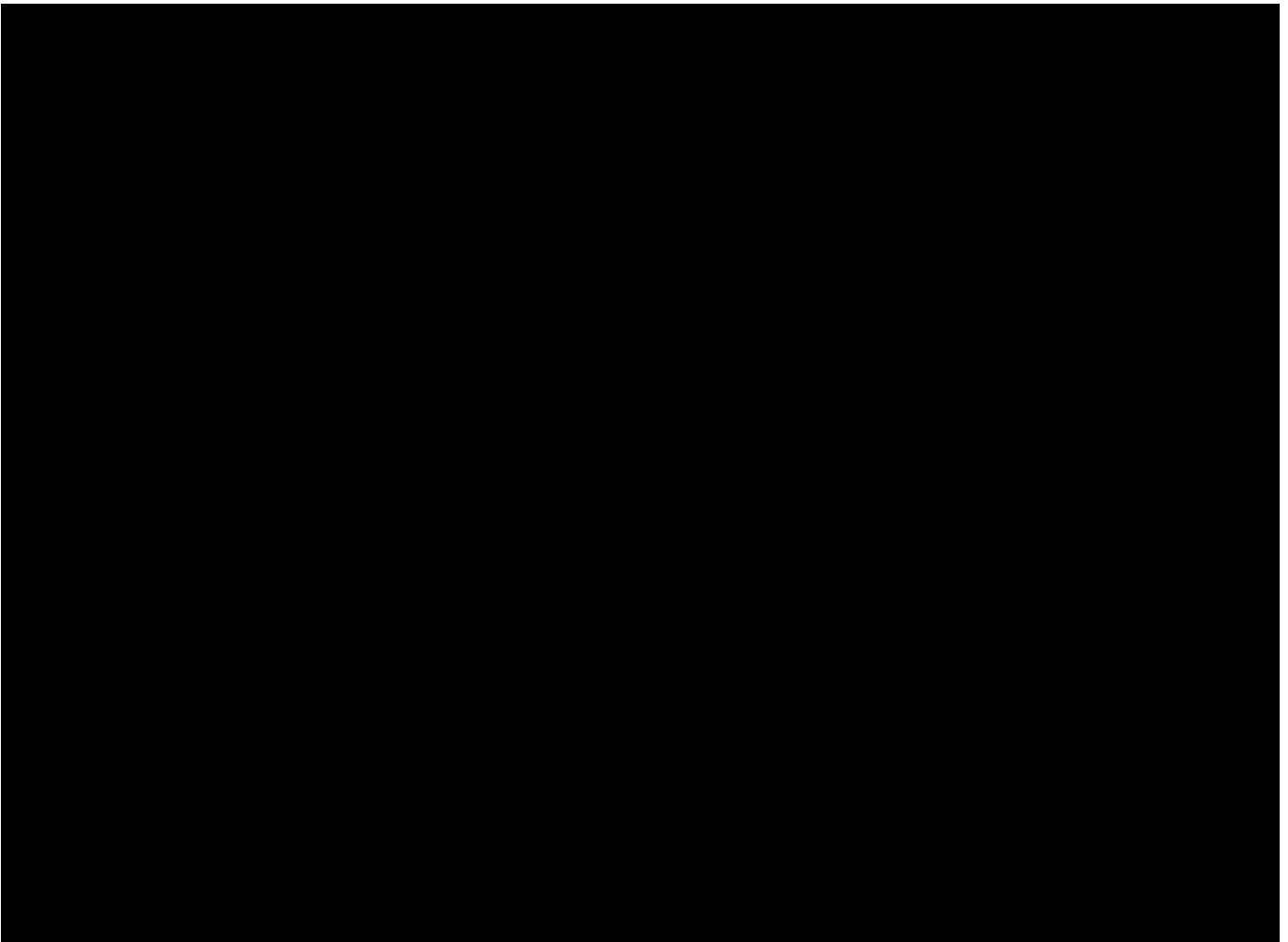
³³ Chintagunta Rep., Ex. 24, at ¶ 81.

³⁴ The only doctor not deposed was Dr. Madison. After attempting to serve a subpoena, Cephalon learned that he had closed his practice and left the state.

³⁵ SOF, Ex. 1, at ¶ 120.

³⁶ SOF, Ex. 1, at ¶¶ 328-29.

³⁷ SOF, Ex. 1, at ¶¶ 146, 362, 401, 471, 517.

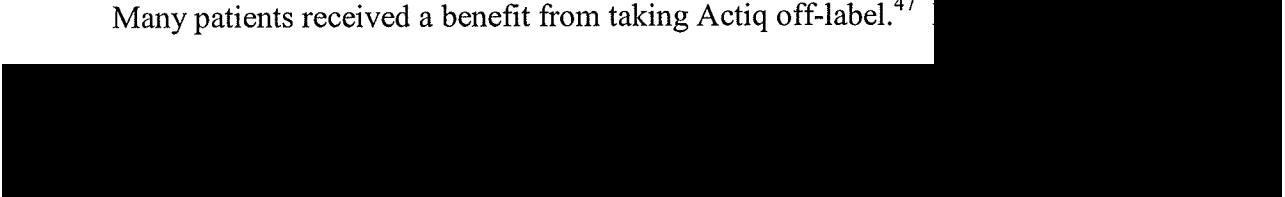


Details of each doctor's prescribing decisions for the prescriptions reimbursed by the named Plaintiffs are set forth in the Cephalon's Statement of Material Facts, attached as Exhibit 1 to the March 20, 2013 Declaration of Jeremy Menkowitz.

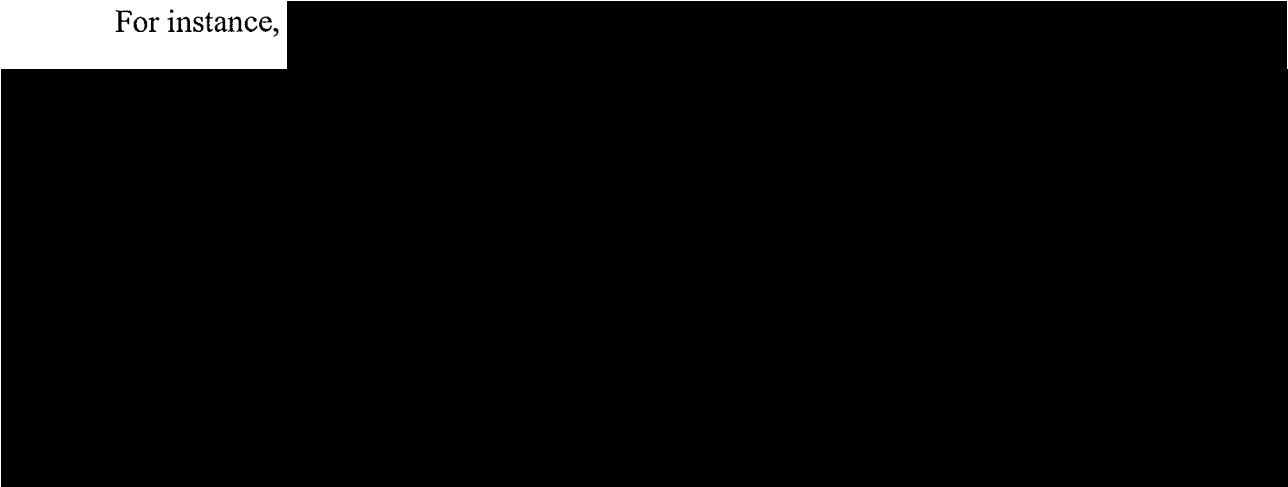
38 SOF, Ex. 1, at ¶¶ 118, 184, 228, 299, 402, 473, 518.
39 SOF, Ex. 1, at ¶ 118.
40 SOF, Ex. 1, at ¶ 350.
41 SOF, Ex. 1, at ¶¶ 363-64.
42 SOF, Ex. 1, at ¶ 361.
43 SOF, Ex. 1, at ¶¶ 352-53.
44 SOF, Ex. 1, at ¶¶ 345, 356-57.
45 SOF, Ex. 1, at ¶ 354.
46 SOF, Ex. 1, at ¶¶ 358-59, 367.

C. Off-Label Prescriptions Of Actiq Helped Patients Control Their Debilitating Pain And Patients Received A Significant Benefit From Those Prescriptions.

Many patients received a benefit from taking Actiq off-label.⁴⁷



For instance,



In fact, one doctor who prescribed Actiq to a PTC insured testified that,



⁴⁷ SOF, Ex. 1, at ¶ 119,
⁴⁸ SOF, Ex. 1, at ¶¶ 139, 190-91, 216, 269, 303, 356, 396, 408, 443, 453, 466, 479, 501, 504, 512.
⁴⁹ SOF, Ex. 1, at ¶¶ 389-91, 395-96.
⁵⁰ SOF, Ex. 1, at ¶¶ 210-11, 214.
⁵¹ SOF, Ex. 1, at ¶ 214.
⁵² SOF, Ex. 1, at ¶ 143.
⁵³ SOF, Ex. 1, at ¶ 119,
⁵⁴ SOF, Ex. 1, at ¶¶ 206, 410, 493.
⁵⁵ SOF, Ex. 1, at ¶ 192.

D. TPPs Are Diverse And Made Individualized And Different Reimbursement Decisions With Respect To Actiq, Based Upon Many Factors.

Plaintiffs allege that Cephalon “forced” each TPP to reimburse for off-label prescriptions of Actiq (Am. Compl., Ex. 2, at ¶ 61), but there is no common evidence of any such “force,” and no common evidence as to why each TPP chose to reimburse for each off-label prescription of Actiq. The term TPP encompasses many different type of entities that pay for health care costs for their insureds.⁵⁶ TPPs include self-funded employer plans (which pay for the claims made by their employees for health benefits),⁵⁷ union health benefit funds (which are set up by multiple employers to pay health care benefits for union workers),⁵⁸ and a variety of traditional insurance and workers’ compensation companies (which sell a variety of health insurance prescription plans both directly to individuals and families and to companies that are not self-funded).⁵⁹

Many factors influence a TPPs decision whether to reimburse for any given drug— regardless of whether the use is on-label or off-label. As explained by Professor David Bradford, the Busbee Chair of Public Policy at the University of Georgia, TPPs have broad discretion as to whether to reimburse for all or only certain prescription medicines, and under what circumstances.⁶⁰ Whether a TPP chooses to do so depends upon its business objectives.⁶¹ For example, because some TPPs may be focused primarily on profit maximization, they may strictly limit what drug will be reimbursed and scrutinize the conditions for which each drug is prescribed.⁶² On the other end

⁵⁶ Report Of David Bradford (“Bradford Rep.”), attached as Ex. 23 to Menkowitz Dec., at ¶¶ 10, 17, 20-25.

⁵⁷ Bradford Rep., Ex. 23, at ¶ 20. Plaintiff Pennsylvania Turnpike Commission (“PTC”) is an example of a self-insured employer that provides group medical benefits, including prescription drug benefits, for its eligible employees. Am. Compl., Ex. 2, at ¶ 12; SOF, Ex. 1, at ¶ 53.

⁵⁸ Bradford Rep., Ex. 23, at ¶ 21. Plaintiff Indiana Carpenters Welfare Fund (“ICWF”) is a self-administered multiemployer union fund which is governed in part by the Taft-Hartley Act. Am. Compl., Ex. 2, at ¶ 11; SOF, Ex. 1, at ¶ 4; *see also* ICWF Rule 30(b)(6) Dep. (“Newman Dep.”), attached as Ex. 6 to Menkowitz Decl., at 50:24-51:16.

⁵⁹ Bradford Rep., Ex. 23, at ¶ 24. Former plaintiff Employers Mutual Casualty Company, EMCASCO Insurance Company and Union Insurance Company (“EMC”) is an example of a health insurance company that covers workers’ compensation claims. Am. Compl., Ex. 2, at ¶ 10; Bradford Rep., Ex. 23, at ¶ 25; EMC Rule 30(b)(6) Dep. (“Knutsen Dep.”), attached as Ex. 7 to Menkowitz Decl., at 10:18–12:22.

⁶⁰ Bradford Rep., Ex. 23, at ¶¶ 31-32.

⁶¹ Bradford Rep., Ex. 23, at ¶¶ 10, 17-18, 28-29.

⁶² Bradford Rep., Ex. 23, at ¶¶ 10, 18-19.

of the spectrum, some TPPs may prioritize choice, ease of access, and comprehensiveness of benefits for their insureds.⁶³ Thus, these TPPs may choose to cover more prescription medicines for their insureds, including off-label prescriptions.⁶⁴ And some TPPs offer multiple products, which fall along different points on the spectrum between strict limits and broad choice.⁶⁵

As Professor Bradford explains, TPPs differ in the extent to which they manage their prescription coverage and costs.

⁶³ Bradford Rep., Ex. 23, at ¶¶ 10, 18-19.
⁶⁴ Bradford Rep., Ex. 23, at ¶ 18.
⁶⁵ Bradford Rep., Ex. 23, at ¶¶ 17-19, 26.
⁶⁶ Bradford Rep., Ex. 23, at ¶¶ 68-70.
⁶⁷ Bradford Rep., Ex. 23, at ¶ 69; SOF, Ex. 1, at ¶¶ 47-48, 89-91.
⁶⁸ Bradford Rep., Ex. 23, at ¶¶ 68-75.
⁶⁹ Bradford Rep., Ex. 23, at ¶¶ 11, 32-33.
⁷⁰ Bradford Rep., Ex. 23, at ¶ 38.

[REDACTED]

Based upon its unique business model, objectives, and sophistication, each TPP made unique reimbursement decisions with respect to Actiq, including whether to reimburse for off-label prescriptions.

[REDACTED]

For example,

[REDACTED]

[REDACTED]

⁷¹ Bradford Rep., Ex. 23, at ¶¶ 43, 59-61.
⁷² Bradford Rep., Ex. 23, at ¶¶ 63, 79 & Ex. 2.
⁷³ Bradford Rep., Ex. 23, at ¶ 76.
⁷⁴ Bradford Rep., Ex. 23, at ¶¶ 79-82.
⁷⁵ Bradford Rep., Ex. 23, at ¶¶ 79-82.
⁷⁶ *Ironworkers*, 634 F.3d at 1366 (defining prior authorization); *see also* Bradford Rep., Ex. 23, at ¶¶ 79-80.
⁷⁷ SOF, Ex. 1, at ¶ 70; Bradford Rep., Ex. 23, at ¶ 51.
⁷⁸ SOF, Ex. 1, at ¶ 27.
⁷⁹ SOF, Ex. 1, at ¶¶ 31-33.
⁸⁰ Bradford Rep., Ex. 23, at ¶ 97.
⁸¹ SOF, Ex. 1, at ¶ 70.

Still other TPPs expressly approved each off-label prescription of Actiq. [REDACTED]

[REDACTED]

In one case, it challenged the medical necessity of a prescription of Actiq for an off-label use, urging that all off-label prescriptions of Actiq are medically inappropriate before a Pennsylvania workers' compensation judge.⁸⁷ It lost this challenge when the judge found that, based upon that patient's medical history, the off-label prescriptions were medically appropriate.⁸⁸ [REDACTED]

Put simply, each TPP that reimbursed for off-label prescriptions of Actiq did so for different reasons, based upon unique sets of facts and circumstances. In a case where Plaintiffs' legal theory turns on the "equities," the many individual issues presented by such divergent facts and circumstances simply cannot be ignored.

⁸² SOF, Ex. 1, at ¶ 74.

⁸³ Knutsen Dep., Ex. 7, at 233:3-235:3; Bradford Rep., Ex. 23, at ¶ 66.

⁸⁴ Knutsen Dep., Ex. 7, at 197:7-23; Bradford Rep., Ex. 23, at ¶ 66.

⁸⁵ Knutsen Dep., Ex. 7, at 71:1-73:24; Bradford Rep., Ex. 23, at ¶ 66.

⁸⁶ Knutsen Dep., Ex. 7, at 79:11-16; Bradford Rep., Ex. 23, at ¶ 66.

⁸⁷ SOF, Ex. 1, at ¶¶ 116-17.

⁸⁸ *Id.*

⁸⁹ SOF, Ex. 1, at ¶¶ 101-02.

E. Actiq Prescriptions May Have Enabled Many TPPs To Avoid More Significant Costs And TPPs May Have Passed On Any Costs That They Incurred For Actiq To Their Insureds.

Plaintiffs contend that each TPP was injured by paying for off-label prescriptions of Actiq. (Am. Compl., Ex. 2, at ¶ 5; Rosenthal Decl., Ex. 19, Doc. No. 348, at ¶ 14). However, there is no common evidence to support this argument either. Indeed, TPPs may have actually avoided much more significant costs as a result of Actiq prescriptions.⁹⁰

Even if TPPs did not save money as a result of off-label prescriptions of Actiq, most TPPs had the ability to recoup their costs through increased premiums.⁹⁶ As explained in detail in *Ironworkers Local Union 68 And Participating Employers Health And Welfare Funds v. Astazeneca Pharm. LP*, 634 F.3d 1352, 1364-66 (11th Cir. 2011), TPPs do not offer their services for free. In exchange for paying for future health care, TPPs charge and receive a “premium,” an up-front fee that represents the price of the insurance policy.⁹⁷ The premiums charged may or may not be

⁹⁰ Bradford Rep., Ex. 23, at ¶¶ 92-94.

⁹¹ SOF, Ex. 1, at ¶¶ 193, 214, 234, 372, 409, 501.

⁹² *Id.*; see also Bradford Rep., Ex. 23, at ¶¶ 93-94.

⁹³ SOF, Ex. 1, at ¶¶ 194, 271, 305, 373, 411, 477.

⁹⁴ Bradford Rep., Ex. 23, at ¶¶ 92-94.

⁹⁵ SOF, Ex. 1, at ¶¶ 193, 373, 411.

⁹⁶ Bradford Rep., Ex. 23, at ¶¶ 86-87.

⁹⁷ Bradford Rep., Ex. 23, at ¶ 87; Rosenthal Dep., Ex. 18, at 63:3-64:22.

sufficient to cover the claims each TPP pays. If any given TPP sustained a loss because prescription medicine costs were more than the premiums, it could (and likely did) seek to recoup these losses from their insureds in the form of increased premiums in subsequent years.⁹⁸ EMC, for instance, factored the costs of workers' compensation claims for one year into the premium that it charged the insured in the next year.⁹⁹ Because different TPPs have different profit maximization constraints,¹⁰⁰ whether a TPP passed on the costs of Actiq to its insureds through higher premiums will vary from TPP to TPP and will turn on individual facts.

F. Plaintiffs Seek Certification Of A Nationwide Class Asserting Unjust Enrichment Claims Under Pennsylvania Law.

As noted, Plaintiffs have abandoned their statutory consumer fraud claims on a class-wide basis. Based exclusively upon their unjust enrichment theory, Plaintiffs seek to certify a nationwide class of "all [TPPs] in the United States who paid and/or reimbursed, in whole or in part, for the cost of Actiq prescribed for indications other than cancer and for consumption by their . . . insureds during the period from January 1, 2002 through December 31, 2006." (Pls. Br., at 2-3). Plaintiffs contend that Pennsylvania law can be applied to the claims of all members of this nationwide class. In the alternative, Plaintiffs seek certification of two classes that are roughly and inexactlly grouped according to where the proposed class members reside—one class is comprised of TPPs in 12 jurisdictions and the other of TPPs in 21 jurisdictions.¹⁰¹ (Pls. Br., at 3). As a further

⁹⁸ SOF, Ex. 1, at ¶¶ 42-45, 104-05.

⁹⁹ SOF, Ex. 1, at ¶¶ 104-105.

¹⁰⁰ Bradford Rep., Ex. 23, at ¶¶ 17-19. For instance, because the terms of union insurance plans are often subject to union negotiations, a plan may trade off health benefits for other benefits or compensation. *Id.* at ¶¶ 21-23, 90. The outcome of the negotiation determines to what extent the plan has the ability to pass on cost increases to its members. *Id.* at ¶ 90. By contrast, self-funded employer plans face slightly different profit maximization concerns. *Id.* at ¶ 89. One benefit of providing a health plan to employees is that it increases employee productivity and retention and helps the company attract a high quality labor force. *Id.* Like a health insurance company, a self-funded employer plan has the option of passing prescription cost increases on to its members. *Id.* But its constraining factor is not simply that employees may look for a different health insurance plan, but that they may look for a different job. *Id.*

¹⁰¹ The first alternative class, defined as the "Unjust Enrichment (Restatement) Class," consists of all TPPs who paid or reimbursed for off-label prescriptions of Actiq in Arkansas, Colorado, Connecticut, the District of Columbia, Hawaii, Illinois, Indiana, Iowa, New Hampshire, New York, Oklahoma, and West Virginia. (Pls. Br., at 3). The second alternative class, defined as the "Unjust Enrichment (Appreciation) Class," consists of TPPs who paid or reimbursed for

alternative, Plaintiffs seek separate classes of all TPPs who reside in either Indiana or Pennsylvania. (Pls. Br., at 3 n.4).

As described below, because Plaintiffs have failed to carry their burden to satisfy the requirements of Rule 23, none of these proposed classes should be certified.

III. LEGAL STANDARD

It is well-settled that “[t]he class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only.” *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2550 (2011) (quotation and citation omitted). To have a class certified, a plaintiff must satisfy all four requirements of Rule 23(a) and must meet one of the provisions of Rule 23(b). Plaintiffs therefore must demonstrate that: (a) the size of the class is so numerous that joinder of all members is impracticable—numerosity; (b) there are questions of law and fact common to the class—commonality; (c) the claims or defenses are typical of the class—typicality; and (d) the representatives will fairly and adequately protect the interests of the class—adequacy of representation. Fed. R. Civ. P. 23(a)(1)–(4). Because Plaintiffs seek monetary relief, they also must demonstrate under Rule 23(b)(3) that common questions of law or fact *predominate* over individual questions, that the class action is manageable, and that it is a superior means of resolving the controversy. Fed. R. Civ. P. 23(b)(3).

Plaintiffs bear the burden of proof by a preponderance of the evidence that they meet these criteria. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 316 n.14, 320–21 (3d Cir. 2008). It is not sufficient for a plaintiff merely to *allege* the class certification requirements. *Dukes*, 131 S.Ct. at 2551. Instead, Plaintiffs bear the burden of affirmatively demonstrating that the [Rule 23] requirements are met, including the “capacity of a class[-]wide proceeding to generate common

off-label prescriptions of Actiq in Alaska, California, Florida, Georgia, Kansas, Kentucky, Maine, Maryland, Massachusetts, Missouri, Nevada, New Mexico, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, and Wisconsin. (*Id.* at 3).

answers apt to drive the resolution of the litigation.” *Id.* at 2551 (emphasis in original); *see also Hydrogen Peroxide*, 552 F.3d at 318 (“A party’s assurance to the court that it intends or plans to meet the [Rule 23] requirements is insufficient”); *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 160 (1982) (“[A]ctual, not presumed, conformance with Rule 23(a) remains . . . indispensable.”).

The Court also has certain obligations when deciding a class certification motion. First, the Court must resolve factual disputes and make factual determinations as part of the Rule 23(a) analysis, typically after an evidentiary hearing. *Hydrogen Peroxide*, 552 F.3d at 320. Second, the Court must conduct a “rigorous analysis” to determine whether Plaintiffs have met their burden of showing the Rule 23 requirements are met, an analysis that “[f]requently . . . will entail some overlap with the merits of the plaintiff’s underlying claim.” *Dukes*, 131 S. Ct. at 2551; *see also Hydrogen Peroxide*, 552 F.3d at 316. Third, to the extent the Court is inclined to grant certification, it must provide “(1) a readily discernible, clear, and precise statement of the parameters defining the class or classes to be certified, and (2) a readily discernible, clear, and complete list of the claims, issues or defenses to be treated on a class basis.” *Wachtel v. Guardian Life Ins. Co. of Am.*, 453 F.3d 179, 187-88 (3d Cir. 2006).

IV. ARGUMENT

Plaintiffs have failed to satisfy their burden under Rule 23, *Dukes*, and *Hydrogen Peroxide* for multiple independent reasons:

- (1) Numerous courts have denied class certification on the very theory of liability that Plaintiffs seek to certify here—that is, claims by TPPs against a pharmaceutical company based upon allegations of off-label promotion.
- (2) There are no key common issues that turn on common evidence and that are capable of resolving each putative class member’s unjust enrichment claim in one broad stroke. Even if one could hypothesize some common issues within the meaning of *Dukes*, those issues do not predominate, as required by Rule 23(b)(3), because:
 - (a) Cephalon did not engage in uniform conduct towards each doctor and TPP;

- (b) doctors prescribed Actiq off-label for many different reasons, and many were not influenced by anything that Cephalon said or did;
 - (c) many off-label prescriptions of Actiq were medically appropriate for and provided a significant therapeutic benefit to patients;
 - (e) many TPPs chose to reimburse for off-label prescriptions of Actiq based upon their knowledge of Actiq and their own independent business objectives, and were not exposed to or influenced by anything that Cephalon said, did, or failed to say or do;
 - (f) many TPPs suffered no injury because they saved costs from off-label prescriptions of Actiq and were able to recoup their costs through their premiums; and
 - (g) Plaintiffs have not provided a viable method for calculating net profits from off-label prescriptions that were the result of any wrongdoing by Cephalon.
- (3) Plaintiffs' proposed nationwide and alternative multi-state classes are unmanageable because, under Pennsylvania choice-of-law principles, the Court must conduct a choice of law analysis of the laws of all 51 jurisdictions, make numerous predictions regarding the unjust enrichments laws of each jurisdiction, and ultimately apply the materially different unjust enrichment laws of multiple jurisdictions.
- (4) Plaintiffs cannot satisfy the remaining requirements for class certification, because:
- (a) Plaintiffs are not adequate class representatives because they have abandoned their statutory consumer fraud claim on a class-wide basis, to the detriment of the proposed classes;
 - (b) Plaintiffs' claims are not typical of the claims of other class members because they received no communications from Cephalon, they consciously chose not to implement controls that would have allowed them to avoid costs for off-label prescriptions of Actiq (if that was their goal), Cephalon did not cause any of the off-label prescriptions to their insureds, and each of their insureds received a benefit from each off-label prescription of Actiq;
 - (c) A class action is not a superior mechanism because the amount of alleged damages sustained by each TPP is substantial and each TPP has an incentive to bring its own claims, to the extent it wants to do so; and
 - (d) Plaintiffs' class definition is fatally overbroad because it includes TPPs who suffered no injury and have no standing to bring claims against Cephalon.

As described below, each of these reasons independently supports the denial of Plaintiffs' class certification motion.

A. Plaintiffs' Class Theory Has Been Repeatedly Rejected By Other Courts.

Courts routinely deny class certification for claims brought by TPPs against pharmaceutical companies based upon allegations of off-label promotion. In such cases, the courts have recognized the insurmountable hurdles to class treatment given the individualized nature of doctors' prescribing decisions and TPPs' reimbursement decisions.

The Second Circuit's decision in *UFCW Local 1776 v. Eli Lilly and Co.*, 620 F.3d 121 (2d. Cir. 2010), is instructive. There, TPPs alleged that Eli Lilly promoted off-label prescriptions for Zyprexa to treat conditions, such as depression, anxiety, and depression, for which plaintiffs claimed that Zyprexa did not provide an effective treatment. *Id.* at 129. After the district court granted class certification, the Second Circuit reversed. The Second Circuit reasoned that individualized issues predominated over any common ones for at least five reasons:

- (1) The TPPs' "theory of causation is interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof." *Id.* at 135. Indeed, because the pharmaceutical manufacturer was not "the *only* source of information on which doctors based prescribing decisions," other factors needed to be considered in determining causation on a prescription-by-prescription basis. *Id.* (emphasis in original);
- (2) Because "at least some doctors were not misled by Lilly's alleged misrepresentations," general proof of causation was "impossible." *Id.* at 135;
- (3) Plaintiffs failed to present "any evidence to show that, had Zyprexa not been prescribed, *no* medication would have been prescribed, nor that possible alternatives . . . would have been less expensive than Zyprexa." *Id.* at 135-36 (emphasis in original);
- (4) "[E]ach TPP and each PBM had to approve Zyprexa's placement on a formulary." *Id.*; and
- (5) Each TPP "covers a different group of insured patients." *Id.* at 136.

Summarizing this evidence, the Second Court held that class certification was improper because "individual physicians prescribing Zyprexa may have relied on Lilly's alleged misrepresentations to different degrees, or not at all, . . . some excess prescriptions may not have

actually caused loss, given the likelihood of substitute prescriptions for other drugs, and . . . different TPPs may have paid for different ‘excess’ quantities of prescriptions.” *Id.* at 136; *see also Sergeants Benevolent Assoc. Health And Welfare Benefit Fund*, No. 08-cv-0179, 2011 WL 824607, at *13-15 (E.D.N.Y. Feb. 16, 2011) (applying *UFCW Local 1776* to deny class certification on RICO claim by third-party payors for recovery of off-label prescriptions of Ketek, because causation cannot be proved by common evidence and reasoning that because “the inherent nature of the prescription process simply does not lend itself to common proof of causation,” there “is simply no way to determine whether all, or even most, of the physicians who previously prescribed Ketek for their patients based their decisions on Aventis’s purported misinformation”), *affirmed by*, 2011 WL 1326365 (E.D.N.Y. March 30, 2011).

Similarly, in *In re Neurontin Mktg., Sales Practices and Products Liab. Litig.*, 257 F.R.D. 315 (D. Mass. 2009), third-party payors who paid for off-label prescriptions of the prescription medicine Neurontin brought a putative class action against Pfizer for allegedly engaging in a “fraudulent campaign to market and sell Neurontin for treatment of ‘off-label’ indications.” *Id.* at 316. The payors asserted RICO, state consumer fraud, and unjust enrichment claims. *Id.* In support of their position, the TPPs submitted an expert report from Professor Rosenthal (Plaintiffs’ damages expert in this case), who attempted to prove causation and injury in the aggregate based upon econometric analysis. *Id.* at 322, 327-28.

Judge Saris denied class certification, rejected Professor Rosenthal’s analysis, and concluded that the Rule 23(b)(3) predominance requirement was not met because “class certification of the TPP subclasses would inevitably result in a tsunami of individual, complex trials.” *Id.* at 333. The Court reasoned that evaluating “the requirement that plaintiffs establish a nexus between the doctor [who made the prescribing decision] and the sales team [promoting Neurontin] will create individualized issues that will inevitably predominate over the common

questions,” including whether the prescribing doctors were ever detailed, whether they were ever detailed about off-label uses, and why each doctor made the prescription decision. *Id.* at 330-31. The Court further reasoned that “in order to establish the requisite causation for the TPPs, plaintiffs would have to present individualized evidence about what information a P & T Committee received regarding Neurontin and how the absence of fraudulent information would have altered Neurontin’s placement within its formulary and how that alternative classification of Neurontin would have saved the TPP money.” *Id.* at 333 (emphasis added). Because Professor Rosenthal’s aggregate damages report could not account for any of these doctor-specific or TPP-specific issues, the Court denied the TPP plaintiffs’ motion for class certification.

Following the logic of *Zyprexa*, *Neurontin*, and *Sergeants Benevolent Assoc.*, state courts have denied analogous class actions for similar theories of liability. *See, e.g., Wyeth, Inc. v. Blue Cross and Blue Shield of Ala.*, 42 So. 3d 1216, 1227 (Ala. 2010) (vacating trial court’s class certification order on unjust enrichment claim by third-party payor against pharmaceutical company based upon payments for prescription medicine); *Int’l Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co.*, 192 N.J. 372, 390-91 (N.J. 2007) (denying certification of class of third-party payors based upon allegedly improper marketing, because individualized inquiries relating to how and why particular third-party payors treated Vioxx overwhelmed questions common to the class, including why each “third-party payor, relying on PBMs and P&T Committees, made individualized decisions concerning the benefits that would be available to its members for whom Vioxx was prescribed”).

Plaintiffs argue that the Court should simply ignore the wealth of adverse authority because “both *Zyprexa* and *Neurontin* involved allegations that the defendant drug companies misrepresented that the drugs were effective for off-label uses when they were not effective for such uses.” (Pls. Br., at 34). Plaintiffs’ argument is nonsensical. That distinction makes the argument

against class certification even stronger here, precisely because Plaintiffs concede that *Actiq* was *effective* in treating off-label conditions. (*Id.* (“Plaintiffs have never alleged that Actiq was ineffective”)). In other words, Plaintiffs concede that their insureds received the full value of what they paid for—an effective pain medicine. This concession alone defeats Plaintiffs’ unjust enrichment claim in most, if not all, states.¹⁰²

Plaintiffs also attempt to avoid these holdings by seeking class certification only on their unjust enrichment claim. However, *Neurontin* and *Wyeth* denied class certification of unjust enrichment claims. In fact, the logic of each of these decisions—*Zyprexa*, *Neurontin*, *Sergeants Benevolent Assoc.*, *Wyeth*, and *Merck*—applies equally to Plaintiffs’ unjust enrichment theory here, because equitable determinations are inherently individualized. As discussed below, resolving the unjust enrichment claim of each class member will require the Court and jury to make a myriad of individualized factual and legal inquiries that make class certification inappropriate for the very reasons other courts have declined to certify such classes.¹⁰³

B. No Class Should Be Certified Because There Are No Key Common Questions Of Fact Capable Of Class-Wide Resolution, And Individualized Factual Issues Will Predominate.

In *Dukes*, the Supreme Court held that a plaintiff seeking class certification must demonstrate that there are “answers to common questions” of law or fact that are “capable of

¹⁰² See, e.g., *Am. Fed’n. & Mun. Employees v. Ortho-McNeil-Janssen Pharms.*, 857 F. Supp. 2d 510, 514-516 (E.D. Pa. 2012) (dismissing unjust enrichment claim under Pennsylvania law in part because “Plaintiffs cannot recover if they ‘paid for an effective pain killer, and [their members] received just that—the benefit of [their] bargain’”); *Emp’r Teamsters-Local Nos. 175/505 Health and Welfare Trust Fund v. Bristol Myers*, No. 12-0587, 2013 WL 360011, at *6 (S.D.W.Va. Jan. 29, 2013) (dismissing unjust enrichment claim because “Defendants’ retention of payments for a product that was effective in its ordinary purpose—though perhaps not as effective compared to other drugs as claimed—[does not] rise[] to the level of constituting unjust enrichment”).

¹⁰³ Plaintiffs contend that none of the medicines at issue in the above cases “posed the serious addiction and overdose concerns that caused the FDA to only approve Actiq for cancer patients.” (Pls. Br., at 34). But, once again, Plaintiffs’ argument lacks merit. Plaintiffs are not seeking to recover any costs associated with addiction- or overdose-related expenses. Nor do Plaintiffs provide any basis to show why the Actiq RMP had anything to do with causation or injury. Indeed, in *Sergeants Benevolent Assoc.*, Judge Reyes rejected a similar argument by the same Plaintiffs’ counsel in this case, reasoning that “while there are differences between the underlying facts, arguments and purported common evidence offered in this and *In re Zyprexa*, those differences are immaterial.” 2011 WL 824607, at *15. Because proving Plaintiffs’ very theory of causation and injury will require individualized assessments of each prescription, each doctor, and each TPP, class certification is inappropriate.

classwide resolution” and that will help resolve the claim at issue in “one stroke.” *Dukes*, 131 S. Ct. at 2551, 2545. Indeed, “[w]hat matters to class certification . . . is not the raising of common ‘questions’—even in droves—but, rather the capacity of a class[-]wide proceeding to generate common *answers* apt to drive the resolution of litigation.” *Id.* (citations omitted). Essentially, this means that a question is “common” only if the proof as to one plaintiff is the same as to all class members. This commonality requirement cannot be met when a claim hinges upon decision-makers—here, thousands of class members and an even greater number of prescribing doctors—exercising discretion in different and individual ways. *Id.*

Plaintiffs must also demonstrate pursuant to Rule 23(b)(3) that “[i]ssues common to the class . . . **predominate** over individual issues.” *In re Prudential Ins. Co. Am. Sales Practice Litig.*, 148 F.3d 283, 313-14 (3d Cir. 1998). In making this determination, the Court may not simply focus on how Plaintiffs intend to prove their claim, but must “take into account [all] the claims, defenses, relevant facts, and applicable substantive law.” *Klay v. Humana, Inc.*, 382 F.3d 1241, 1254 (11th Cir. 2004) (internal citations omitted); *see also Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 147-49 (3d Cir. 1998) (affirming denial of class certification in part because of individualized issues concerning how defendants intended to defend plaintiffs’ claims). Indeed, “[b]ecause the ‘nature of the evidence that will suffice to resolve a question determines whether the question is common or individual,’ ‘a district court must formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate in a given case.’” *Hydrogen Peroxide*, 552 F.3d at 311 (internal citations omitted). Thus, “[i]f proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable.” *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 172 (3d Cir. 2001).

Applying these principles, courts have recognized that, as a general matter, unjust enrichment claims should not be certified because “common questions [of fact] **will rarely, if ever,**

predominate an unjust enrichment claim.” *Vega v. T-Mobile USA, Inc.*, 564 F.3d 1256, 1274 (11th Cir. 2009) (emphasis added). This is because each claim turns on individualized facts about the equities concerning each transaction. *See* 1 McLaughlin on Class Actions § 5:60 (9th ed.) “[t]he majority view is that unjust enrichment claims usually are not amenable to class treatment because the claim requires evaluation of the individual circumstances of each claimant”).

As explained in detail in section IV(C) below, controlling Supreme Court and Third Circuit authority require that the Court engage in a choice of law analysis to determine what law applies to each claim of each class member. *See, e.g., Klaxon v. Stentor Electric Mfg. Co.*, 313 U.S. 487, 496 (1941); *Powers v. Lycoming Engines*, 328 F. App’x. 121, 124 (3d Cir. 2009). This choice of law determination renders Plaintiffs’ proposed class action unmanageable, because the Court would have to predict and ultimately apply the unjust enrichment laws of each state where each putative class member resides, and those laws differ in many important ways. *Powers*, 328 F. App’x. at 124. This defeats Plaintiffs’ proposed class action. *See, e.g., Castano v. Am. Tobacco Co.*, 84 F.3d 734, 741 (5th Cir. 1996) (“[i]n a multi-state class action, variations in state law may swamp any common issues and defeat predominance”).

Nonetheless, even assuming the Court could apply the law of Pennsylvania to all claims by all class members across the country, Pennsylvania law requires the Court in an unjust enrichment case to consider “the *unique factual circumstances of each case . . .*” *MetroClub Condo. Ass’n v. 201-59 N. Eighth St. Assocs., L.P.*, 47 A.3d 137, 148 (Pa. Super. Ct. 2012) (emphasis added) (internal quotations omitted). To succeed on an unjust enrichment claim under Pennsylvania law, each TPP will need to show that it conferred a benefit on Cephalon, that Cephalon appreciated that benefit, and that, based upon the factual circumstances of that transaction, “it would be inequitable for defendant to retain the benefit without payment of value.” *Sovereign Bank v. BJ’s Wholesale Club, Inc.*, 533 F.3d 162, 180 (3d Cir. 2008) (quoting *Limbach Co. LLC v. City of Philadelphia*,

905 A.2d 567, 575 (Pa. Cmwlth. 2006)). The “most important factor to be considered in applying the doctrine is whether the enrichment of the defendant is unjust.” *Walter v. Magee-Womens Hospital of UPMC Health Sys.*, 876 A.2d 400, 407 (Pa. Super. Ct. 2005) (internal citations omitted).

In order to determine whether it would be “inequitable” or “unjust” for Cephalon to retain the proceeds from off-label prescriptions of Actiq, the jury will be required to decide:

- whether and to what extent each doctor was exposed to, and influenced by, any off-label marketing when prescribing Actiq;
- whether the prescription was medically unnecessary for a given patient, and whether the patient received a therapeutic benefit from the prescription;
- whether each doctor would have made a different prescribing decision in the absence of some alleged act or failure to act by Cephalon;
- why each TPP reimbursed for the Actiq prescription at issue, including whether it did so with full knowledge that the prescription was for an off-label condition;
- whether and to what extent each TPP’s reimbursement decision was influenced by anything Cephalon said, did, or failed to say or do; and
- whether the TPP suffered any financial loss as a result of paying for the off-label prescription of Actiq, including whether the TPP received full value for the payment, whether the prescription saved the TPP costs in comparison to alternative therapies, and whether the TPP recouped any costs through its premiums.

As described below, because each of these necessary inquiries can only be answered through examination of the individualized circumstances of each prescription and reimbursement decision. There are no key common questions of fact capable of class-wide resolution and individualized factual issues will predominate.

1. There Is No Common Class-Wide Evidence Demonstrating Whether And To What Extent Each Doctor Was Exposed To Or Influenced By Any Off-Label Marketing When Prescribing Actiq.

Plaintiffs seek recovery for off-label payments that were purportedly made as a result of Cephalon’s alleged “scheme” both to “push Actiq for non-cancer patients” through off-label promotion and alleged failure to prevent off-label prescribing decisions by following the Actiq

RMP. (Pls. Br., at 32). To prove an unjust enrichment claim under Pennsylvania law, there must be some connection between Cephalon's alleged conduct and Plaintiffs' alleged detriment. *See, e.g., Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 936-37 (3d Cir. 1999) (denying unjust enrichment claim for lack of proximate causation and "remoteness of plaintiffs' injuries from defendants' wrongdoing"); *Pa. Emp. Benefit Trust Fund v. Zeneca, Inc.*, 710 F. Supp. 2d 458, 485 (D. Del. 2010) (holding that third-party payor failed to establish unjust enrichment claim under Pennsylvania law because of lack of "requisite causal nexus" between alleged wrongful conduct and injuries suffered); *Commonwealth v. Ortho-McNeil-Janssen Pharms., Inc.*, 52 A.3d 498, 513 (Pa. Commw. Ct. 2012) ("because the Commonwealth did not prove causation. . . [it] did not prove any retention was unjust").¹⁰⁴

This causation requirement under Pennsylvania law means that each TPP must prove that Cephalon's alleged off-label marketing caused each doctor to write each prescription of Actiq and caused each TPP to reimburse. There is no common, class-wide evidence that allows Plaintiffs to do so, because the evidence shows that many doctors were not exposed to Cephalon's promotional activities for Actiq and because a doctor's decision to prescribe Actiq is influenced by numerous factors that are unique to each doctor and patient.¹⁰⁵

¹⁰⁴ At a minimum, a putative class member who could not demonstrate this causal nexus would have no standing under Article III to assert a claim against Cephalon. *See, e.g., In re Schering Plough Corp.*, 678 F.3d at 246.

¹⁰⁵ *See* Chintagunta Rep., Ex. 24, at ¶¶ 37-50 (describing how doctors had different exposure to communications about Actiq); *id.* at ¶¶ 51-84) (describing how doctors prescribed Actiq for many different reasons that are unique to each doctor and patient).

¹⁰⁶ 2005 Marketing Plan, attached as Ex. 32 to Menkowitz Decl., at p. 10 (CEP_TPP_10048145).

[REDACTED]

[REDACTED] As a result, individualized inquiry is needed to determine whether and to what extent each doctor was exposed to the alleged off-label promotion.

There is no common, class-wide proof as to why doctors wrote the off-label prescriptions at issue. [REDACTED]

[REDACTED]

107 SOF, Ex. 1, at ¶¶ 328-29.
108 SOF, Ex. 1, at ¶ 361.
109 SOF, Ex. 1, at ¶¶ 146, 362, 401, 517.
110 SOF, Ex. 1, at ¶ 223.
111 SOF, Ex. 1, at ¶ 471.
112 Dr. Rosenthal testified [REDACTED]

113 Chintagunta Rep., Ex. 24, at ¶¶ 77-84.

Because they cannot, Plaintiffs have not attempted to offer any proof that is common to the proposed classes with respect to causation. Indeed, Plaintiffs' trial plan does not address causation and Plaintiffs offer no causation expert. Both of Plaintiffs' experts conceded during their depositions that they are not offering an opinion on causation.¹¹⁶ Instead, Plaintiffs' causal theory consists of an *assumption* based on their faulty reading of the Actiq RMP. Plaintiffs contend that because the RMP required Cephalon to take certain steps to educate doctors when off-label prescriptions for "groups of physicians (such as a particular specialty)" became "greater than 15% of total quarterly Actiq prescriptions," that document alone demonstrates that any off-label prescriptions above 15% (of all specialties *combined*) necessarily were caused by Cephalon's actions or inactions. (Pls. Br., at 34; Rosenthal Decl., Ex. 19, Doc. No. 348, at ¶ 14 (assuming "that all off-label uses of Actiq in excess of 15% of total prescriptions are subject to damages"))).

But the Actiq RMP does nothing of the sort. As established by Dr. Gottlieb and Professor Chintagunta, the Actiq RMP did not state that marketing, much less off-label marketing, is the presumptive cause of off-label prescriptions.¹¹⁷ In fact, the RMP makes no statement of any kind as to *any* cause of off-label prescribing.¹¹⁸ As Plaintiffs' experts have conceded,

¹¹⁴ SOF, Ex. 1, at ¶¶ 118, 120; *see also id.*, at ¶¶ 133-34, 139, 147, 162, 167-70, 183, 185, 188, 205-07, 216, 224, 227, 229, 246-49, 257, 266, 268-69, 283-84, 298, 303, 324, 328-29, 345-46, 359, 363-64, 369, 385, 396, 403, 406-08, 432-33, 443, 450, 453, 458, 465-66, 472, 474, 492-93, 500-01, 504, 507, 512, 522-23.

¹¹⁵ As Plaintiffs' expert acknowledged, doctors respond differently to the information they receive, "not all doctors react the same to marketing," and "not all doctors increased their prescribing following a detailing [visit]" Rosenthal Dep., Ex. 18, at pp. 110:10-113:22.

¹¹⁶ Rosenthal Dep., Ex. 18, at 72:3-5; Leiderman Dep., Ex. 20, at 41:2-5.

¹¹⁷ Gottlieb Rep., Ex. 26, at ¶¶ 48-55; Chintagunta Rep., Ex. 24, at ¶¶ 29-33.

¹¹⁸ Gottlieb Rep., Ex. 26, at ¶¶ 48-55; Chintagunta Rep., Ex. 24, at ¶¶ 29-33.

Put simply, the RMP says nothing about causation and does not satisfy Plaintiffs' obligation to show that causation can be proven by class-wide proof.¹²⁰

In fact, Plaintiffs' theory presents even more individualized questions of fact. Pursuant to the Actiq RMP, Cephalon was required, in certain circumstances, to provide specific doctors with educational information about the approved indication and risks of Actiq.¹²¹ It did so on multiple occasions.¹²² Thus, it would be necessary to identify who received such educational information, when they received it, and whether each prescriber continued to prescribe Actiq for off-label uses after receiving that information.

—thus negating Plaintiffs' unsupported hypothesis that, had Cephalon taken affirmative educational measures as described in the RMP, the doctors receiving such information would not continue to prescribe Actiq for off-label purposes.¹²³ To the extent that doctors did not receive any of the educational information, the jury would be required to decide—for each doctor—whether he or she would have made a different prescribing decision if he or she had received that information.

2. **There Is No Common Class-Wide Evidence Regarding Whether And To What Extent Each TPP Was Exposed To Or Influenced By Any Off-Label Marketing When Deciding Whether To Reimburse For Each Off-Label Prescription Of Actiq.**

Causation must also be evaluated at the TPP level, too. If TPPs paid for off-label prescriptions of Actiq based upon, *inter alia*, their own business decision to provide more benefits and choices to their insureds, a formulary decision to reimburse for Actiq under certain

¹¹⁹ Liederman Dep., Ex. 20, at 269:18-270:12; Rosenthal Dep., Ex. 18, at 79:9-12, 18-20; 82:13-21.

¹²⁰ Liederman Dep., Ex. 20, at 271:17-273:9 (acknowledging that there is no link between off-label promotion and 15% threshold of Actiq RMP); Rosenthal Dep., Ex. 18, at 82:2-21 (conceding that she performed no analysis to determine that off-label usage would have been 15% but for alleged off-label promotion, and she was not aware of any analysis conducted by FDA).

¹²¹ RMP, Ex. 58, at § 9.1.1.

¹²² See RMP Template Letter, attached as Ex. 28 to Menkowitz Decl.; Cephalon RMP Correspondence Identifying Off-label Prescribers, attached as Ex. 121 to Menkowitz Decl. (identifying Actiq off-label prescribers and instructing that “these physicians [be] educated on our label and Actiq’s RMP”).

¹²³ SOF, Ex. 1, at ¶¶ 186, 261, 519.

circumstances, or after approving a claim upon reviewing the patient's medical information, then such TPPs cannot meet their burden of showing it would be "unjust" for Cephalon to retain its profits from those prescriptions. *See, e.g., Steamfitters*, 171 F.3d at 936-37; *see also Ironworkers*, 634 F.3d at 1358-59, 1368-69 (11th Cir. 2011) (dismissing unjust enrichment claims under Pennsylvania law because TPPs made independent business decisions to pay for off-label prescriptions and, as a result, pharmaceutical company did not cause those payments); *Neurontin*, 257 F.R.D. at 330-31 (denying class certification on this ground).

There is no common class-wide proof as to why each TPP decided to reimburse for off-label prescriptions of Actiq – much less as to whether Cephalon influenced those decisions in any way. Some TPPs had no contact at all with Cephalon, and thus made their reimbursement decisions independent of any conduct by Cephalon.

At trial, an individualized inquiry will need to be conducted to determine whether there was any contact, and, if so, whether any communications had any impact on each TPP's decision to reimburse for off-label prescriptions of Actiq.

Second, regardless of whether TPPs communicated with Cephalon, TPPs made different decisions to reimburse for off-label prescriptions based upon many different factors. Many TPPs decided to reimburse for off-label prescriptions of Actiq with knowledge that they were doing so.¹²⁶

¹²⁴ SOF, Ex. 1, at ¶¶ 47-48, 89-93.

¹²⁵ Bradford Rep., Ex. 23, at ¶¶ 68-74.

¹²⁶ Bradford Rep., Ex. 23, at ¶¶ 84-85.

¹²⁷ SOF, Ex. 1, at ¶¶ 67-70.

[REDACTED]

[REDACTED] Because those TPPs made their own independent decisions to reimburse for specific off-label prescriptions, they cannot claim that it was somehow “unjust” for Cephalon to retain the profits resulting from the TPPs’ conscious decisions.

For those TPPs who chose not to impose any restrictions on off-label prescriptions of Actiq, a jury will need to consider why the TPP chose not to do so, including whether the TPP wanted to provide Actiq coverage to all insureds regardless of their condition because it was an effective pain medicine.¹²⁹ For instance, [REDACTED]

[REDACTED]

To the extent ICWF and other putative class members paid for off-label prescriptions of Actiq, this was a matter of choice—and not because of anything that Cephalon did or did not do.¹³²

In short, TPPs chose to reimburse for off-label prescriptions of Actiq for many different reasons, and many of these reasons had nothing to do with Cephalon. As a result, there is no common class-wide proof showing that all TPPs reimbursed for off-label prescriptions of Actiq because of Cephalon’s alleged off-label marketing.

3. There Is No Common Class-Wide Evidence As To The Medical Appropriateness Of Off-Label Prescriptions Of Actiq.

Also fatal to Plaintiffs’ motion is their need to prove that each off-label prescription was unnecessary or inappropriate. (Pls. Am. Compl., at ¶¶ 1, 5 (alleging that Plaintiffs paid for

¹²⁸ [REDACTED]

¹²⁹ See Bradford Rep., Ex. 23, at ¶¶ 17-19, 28-30.

¹³⁰ SOF, Ex. 1, at ¶¶ 13-24, 31-34, 36; Bradford Rep., Ex. 23, at ¶¶ 46-48.

¹³¹ SOF, Ex. 1, at ¶¶ 99-103; Bradford Rep., Ex. 23, at ¶¶ 55-58.

¹³² Still other TPPs may have made the business judgment to reimburse for off-label prescriptions because of other concerns, such as the costs of imposing controls on prescription medicines.

“inappropriate” and “medically unnecessary” prescriptions of Actiq); *Ironworkers*, 634 F.3d at 1360 (to establish economic injury, each TPP must establish that each prescription for which it seeks reimbursement was “unnecessary or inappropriate according to sound medical practice”). Any inquiry into whether a prescription was necessary or appropriate would require not only a highly-individualized assessment of each doctor’s exercise of medical judgment when deciding how to treat his or her patient, but also an individual evaluation of how each patient may have benefited from Actiq.

Perhaps recognizing this problem, Plaintiffs urge an extreme and unsupportable position that *all* off-label prescriptions of Actiq are inappropriate. (Pls. Br., at 1 (Actiq “should never be used outside its approved indication”)). But this is contrary to what the Supreme Court, the Third Circuit, and the FDA have held. *See, e.g., Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 351 n.5 (2001) (recognizing that off-label prescribing “often is essential to giving patients optimal medical care”) (internal citations and quotations omitted); *In re Schering Plough Corp.*, 678 F.3d at 246 (“Prescription drugs frequently have therapeutic uses other than their FDA-approved indications”); *In re Actimmune*, 614 F. Supp. 2d at 1041 n.1 (“Physicians . . . may lawfully prescribe a drug for ‘off-label’ indications to achieve therapeutic goals other than those for which the drug was approved.”); *Use of Approved Drugs for Unlabeled Indications*, FDA Drug Bulletin, Vol. 12, No. 1, at 4-5 (April 1982) (“accepted medical practice often includes drug use that is not reflected in the approved drug labeling”).

Notably, the Pennsylvania Workers’ Compensation Office of Adjudication determined that a claimant’s off-label use of Actiq to treat break-through pain associated with a severe spinal injury was medically appropriate, reasonable, and necessary, because it “has measurably improved his

quality of life for his now 7-year old, work-related, persistent, permanent chronic condition.”¹³³ In reaching this decision, the administrative law judge rejected the very argument that Plaintiffs present here—that all off-label prescriptions of Actiq are medically inappropriate. The administrative judge agreed that “there is no precise standard protocol for chronic, non-malignant pain” and that Actiq was effective and reasonable to treat the claimant’s breakthrough pain in that case.¹³⁴

Plaintiffs’ experts concede this point. Dr. Rosenthal opines that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This necessarily requires an individualized prescription-by-prescription analysis.

Plaintiffs’ contention that the RMP renders all off-label prescriptions of Actiq medically inappropriate (Pls. Br, at 2, 34) is contrary to the law and the evidence, including Plaintiffs’ experts’

¹³³ *Gordon v. Borough of Bernville/Kline Process Sys.* (Pa. Workers’ Compensation Office of Adjudication), Claim No. 2471000, Ex. 116, at 9.

¹³⁴ *Id.* at 8; *see also Vono v. State Office of Risk Management*, Dkt. NO. 453-04-5346.M5, at 2-3 (Tex. State Office of Administrative Hearings, Nov. 5, 2004) (finding that off-label usage of medications is common and accepted in the medical community and that Actiq was medically necessary for the treatment of claimant’s chronic non-cancer pain), attached hereto as Ex. 115.

¹³⁵ Rosenthal Dep., Ex. 18. at 80:9-25.

¹³⁶ Leiderman Dep., Ex. 20, at 300:9-301:3.

¹³⁷ *Id.* at 305:7-306:15.

admissions. The FDA does not regulate the practice of medicine or forbid off-label use by doctors.¹³⁸ Nor does it dictate what is medically appropriate for a given patient.¹³⁹ Rather, the practice of medicine is governed by state medical boards, which recognize that the appropriateness of treatment decisions must be evaluated on an individual basis.¹⁴⁰ The specific standards set by medical boards vary from state to state.¹⁴¹

4. There Is No Common Class-Wide Evidence As To Whether Each TPP Actually Suffered An Injury Or Detriment.

Related to the causation element is the requirement under Pennsylvania law that Plaintiffs also must demonstrate that each member of the class suffered an injury or detriment sufficient to permit recovery under the applicable unjust enrichment law. *See, e.g., Ironworkers*, 634 F.3d at 1359 (dismissing unjust enrichment claim under Pennsylvania and other states' laws for lack of injury); *Am. Fed'n. & Mun. Employees*, 857 F. Supp. 2d at 514 ("Plaintiffs also must be able to show they suffered a loss in order to proceed with UTPCPL and unjust enrichment claims"); *Am. & Foreign Ins. Co.v. Jerry's Sport Center, Inc.*, 2 A.3d 526, 615 (Pa. 2010) ("the doctrine of unjust enrichment contemplates that '[a] person who has been unjustly enriched *at the expense of another* must make restitution to the other'" (emphasis added) (internal citations omitted)). At a minimum, a putative class member who never suffered an injury would have no standing to assert a claim against Cephalon. *See, e.g., In re Schering Plough Corp.*, 678 F.3d at 246.

¹³⁸ See Gottlieb Rep., Ex. 26, at ¶¶ 14, 23-26; *see also supra* fn. 6.

¹³⁹ See FDA, Guidance for Industry, Development and Use of Risk Minimization Action Plans, Office of New Drugs, effective March 2005, attached as Ex. 123 to Meknowitz Decl. ("FDA *does not have authority* under these provisions to control decisions made by qualified healthcare practitioners to prescribe products for conditions other than those described in FDA approved professional labeling, or to otherwise regulate medical or surgical practice.") (emphasis added); Gottlieb Rep., Ex. 26, at ¶¶ 5-6, 23-55; Leiderman Dep., Ex. 20, at 100:12-20; 130:10-13 ("FDA does not regulate any individual practitioner" and did not have the authority to regulate the practice of medicine during the class period); Rosenthal Dep., Ex. 18 at 109:8-12 (FDA could not and did not restrict doctor's ability to write prescriptions of Actiq during class period); *see also* 37 Fed. Reg. 16,503, 16,503-16,504 (Aug. 15, 1972); 21 C.F.R. § 312.2(d).

¹⁴⁰ Dr. Leiderman agreed with the Model Policy Of The Federation Of State Medical Boards that "allegations of inappropriate pain management [of opioids] will be evaluated on an individual basis." Model Policy, Ex. 58, at Section 1, p. 3. This Model Policy has been adopted in whole by some states (such as Virginia), in part by other states (such as California), and not at all in other states (such as Indiana). *See supra* fn. 13.

¹⁴¹ Leiderman Dep., Ex. 20, at 88:11-89:11.

Here, Plaintiffs have not and cannot demonstrate injury through class-wide proof. Whether each TPP actually suffered a financial loss depends on a number of individual factors, separate from the cost of reimbursement. First, as a matter of Pennsylvania law, a party is not injured—and there can be no unjust enrichment claim—when there is a full “exchange of value” between the parties. *Villoresi v. Femminella*, 856 A.2d 78, 84 (Pa. Super. Ct. 2004). Relying upon this principle, Pennsylvania courts have repeatedly rejected unjust enrichment claims by TPPs for the cost of a prescription medicine which is alleged to be unsafe when the medicine is otherwise effective for its intended purpose. *See, e.g., In re Avandia Mktg., Sales Practices, & Prods. Liab. Litig.*, MDL No. 1871, 2011 WL 4006639, at *3 (E.D. Pa. Sept. 7, 2011) (where plaintiff alleged that Avandia was not safe and that GSK knew it was unsafe but promoted the drug anyway, but did not allege that Avandia did not serve its intended purpose of reducing blood-sugar levels, there was no claim for unjust enrichment).¹⁴²

Plaintiffs concede that Actiq is effective in treating pain, including pain caused from conditions other than cancer. (Pls. Br., at 34 (“Plaintiffs have never alleged that Actiq was ineffective”)).

Although Plaintiffs contend that Actiq posed “serious addiction and overdose concerns” (*id.*), they do not contend that any insured suffered such issues. They certainly do not seek to recover the costs for any addiction treatment and cannot do so on a class-wide basis because this, too, would be highly individualized. At a minimum, each prescription of Actiq for which each putative class member seeks recovery would

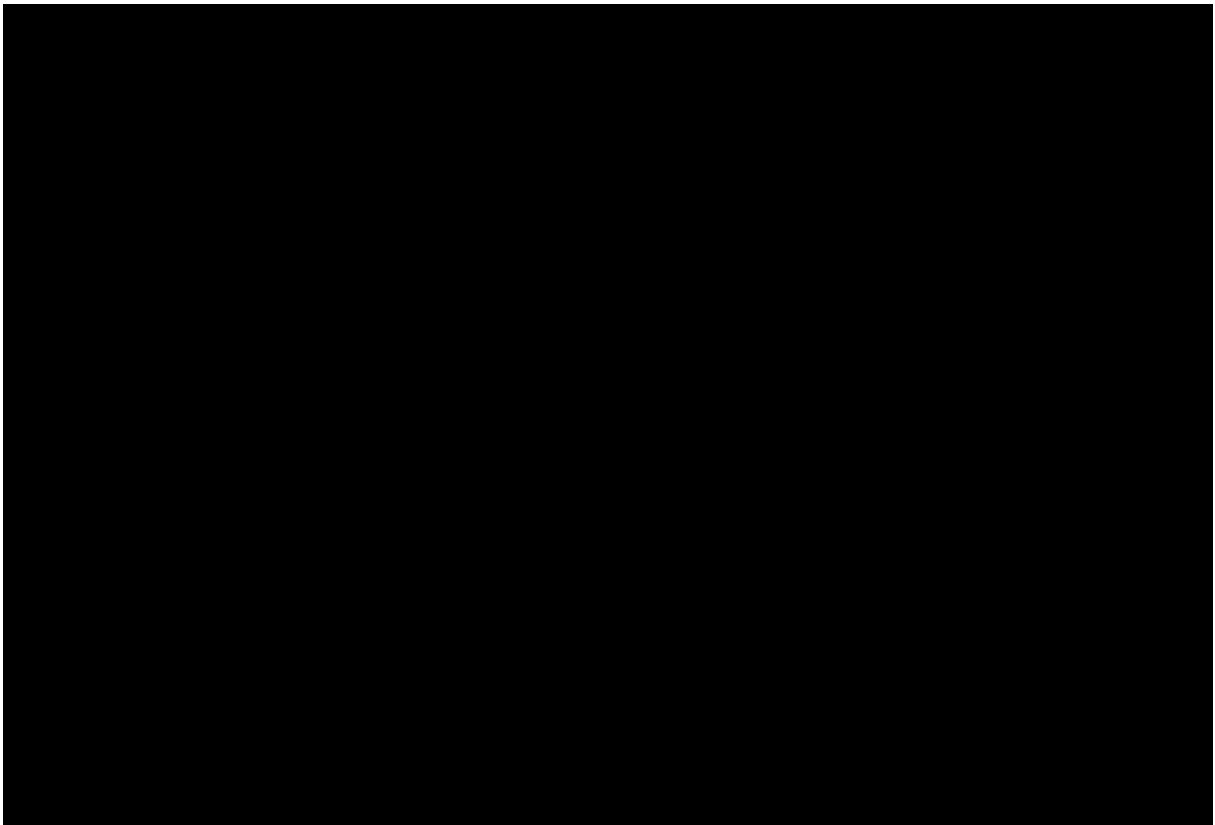
¹⁴² See also *Am. Fed’n. & Mun. Employees*, 857 F. Supp. 2d at 514-515 (dismissing unjust enrichment claim under Pennsylvania law in part because “Plaintiffs cannot recover if they ‘paid for an effective pain killer, and [their members] received just that—the benefit of [their] bargain’”); *Albertson v. Wyeth, Inc.*, 63 Pa. D. & C. 4th 514, 2003 WL 21544488, at *3 (Phila. Ct. Com. Pl. 2003) (“[P]laintiffs did receive the product they sought, a hormone replacement therapy. Plaintiffs merely allege that Prempro was not safe, and that Wyeth knew it was unsafe but promoted the drug anyway. These allegations are insufficient to state a claim for unjust enrichment”).

¹⁴³ SOF, Ex. 1, at ¶ 119.

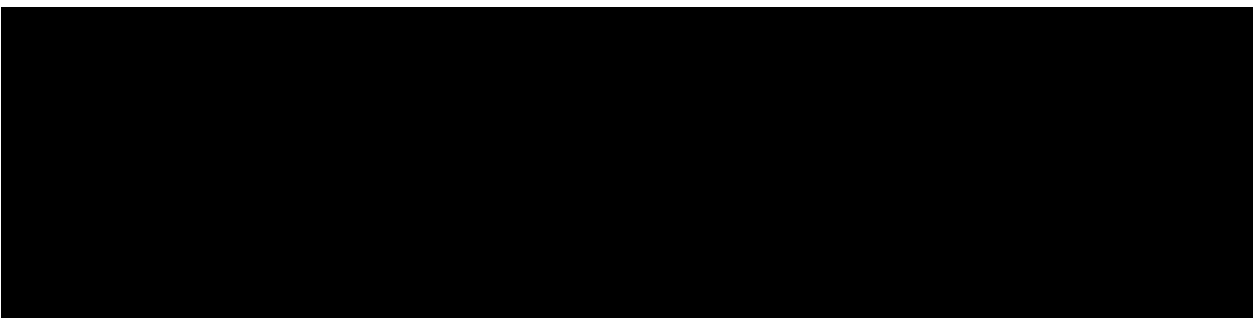
need to be analyzed to determine whether Actiq was effective and whether there was a full exchange of benefit and value.

Second, Plaintiffs have alleged in the complaint that, for each insured, other less expensive treatments were available and more appropriate than Actiq. (Am. Compl., Ex. 2, at ¶ 5). But Plaintiffs have failed to offer evidence of any such treatments—much less a treatment that would be common to the class. The nature and cost of any alternative medicine will depend on each patient's diagnosis and medical history.¹⁴⁴ In addition, the jury will have to determine whether the particular TPP would have paid for those alternative medicines. The avoidance of other medical treatment costs would need to be taken into account in calculating whether they were less expensive and more appropriate than Actiq. This will differ by patient.

For these very reasons, prescribing doctors have testified that prescriptions of Actiq actually *saved health care costs* for TPPs in certain instances:



¹⁴⁴ Bradford Rep., Ex. 23, at ¶¶ 92-94.



Whether off-label prescriptions of Actiq reduced health care costs for TPPs will require yet another individualized inquiry.

Finally, to varying degrees, TPPs pass-through prescription costs in the form of higher premiums or copayments, in which case they suffered no financial loss from reimbursing for off-label prescriptions. As explained by Professor Bradford, whether this occurred is likely to differ by TPP, depending upon its sophistication, makeup, size, and prescription drug plan.¹⁴⁶ Once again, there is simply no common proof.¹⁴⁷

5. There Is No Common Class-Wide Evidence Of Damages.

The Third Circuit has held that the “inquiry for a district court at the class certification stage is whether the plaintiffs have demonstrated by a preponderance of the evidence that they will be able to measure damages on a class-wide basis using common proof.” *Behrend v. Comcast Corp.*, 655 F.3d 182, 204 (3d Cir. 2011), *cert granted in part*, 132 S.Ct. 24 (June 25, 2012); *see also Hydrogen Peroxide*, 552 F.3d at 325. Although “[s]ome variation of damages among class members does not defeat certification,” “[c]omplex and individual questions of damages, however, weigh against finding predominance.” *Behrend*, 655 F.3d at 204; *see also Newton*, 259 F.3d at 187

¹⁴⁵ SOF, Ex. 1, at ¶¶ 409-411; Tuley Dep., Ex. 15, at 30:23-31:23.

¹⁴⁶ Bradford Rep., Ex. 23, at ¶¶ 17-19, 21-23.

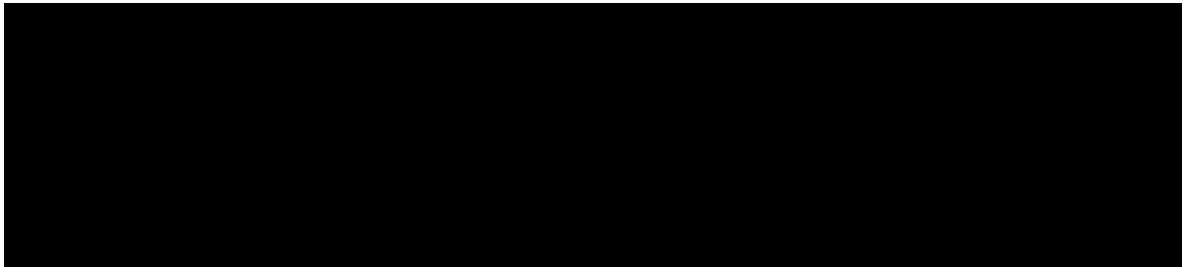
¹⁴⁷ *See, e.g., Ironworkers*, 634 F.3d at 1360 (dismissing unjust enrichment claims for lack of injury because each TPP “would have charged its enrollees higher premiums than it would have if its policies offered more limited prescription drug coverage” and because “these higher premiums, in turn, would compensate the insurer for its increased number of prescription payments, including payments for prescriptions that were medically unnecessary or inappropriate”).

(reasoning that having to examine proof of the circumstances of numerous individual transactions counseled against finding predominance).

Here, the amount of any damages will vary by TPP. Each TPP paid for different off-label prescriptions of Actiq, for different amounts, over different periods of time. More fundamentally, any disgorgement calculation still must determine which off-label prescriptions were somehow “unjust.” This, in turn, would require an individualized analysis into the merits of each prescription, including whether it was written because of anything that Cephalon said or did, whether it was medically appropriate, and why each TPP chose to reimburse for that prescription. This, of course, will differ from TPP to TPP, and from prescription to prescription.

Plaintiffs have not satisfied their burden of demonstrating that damages can be established through common, class-wide proof for any of their proposed classes. Plaintiffs rely exclusively upon the expert report of Professor Rosenthal to meet their burden. As described in Cephalon’s accompanying *Daubert* motion, Rosenthal’s opinion should be excluded as a matter of law. Even if it is not excluded, it is not entitled to any weight for many reasons:

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- Second, Rosenthal wrongly assumed that all off-label prescriptions (above 15%) were caused by Cephalon’s alleged off-label promotion;¹⁴⁹
- Third, Rosenthal used a flawed methodology to reach her conclusion about the number of off-label prescriptions of Actiq. Her estimates for Actiq prescriptions are based on

¹⁴⁸ Rosenthal Dep., Ex. 18, at 57:25-59:13; 60:23-62:1; 68:2-69:4; 69:17-70:3; 100:4-101:23; 107:2-16; 118:14-119:2; 119:16-25; 134:5-135:5; 143:24-144:7..

¹⁴⁹ Chintagunta Rep., Ex. 24, at ¶¶ 22-36.

minuscule samples, samples that do not represent the entire population of doctors prescribing Actiq, and diagnosis coding that is unreliable;¹⁵⁰

- Fourth, Rosenthal is not qualified as an expert cost accountant and has not used a proper accounting methodology to calculate net profits; she relied upon a flawed starting point and ignored important categories of costs which materially affected her calculation of Actiq's profitability;¹⁵¹ and
- Fifth, Rosenthal makes no effort to quantify profits, much less damages, for either of Plaintiffs' alternative class definitions. (See Rosenthal Decl., Doc. No. 348, at ¶ 11 n. 29). Plaintiffs' class certification motion fails as to those proposed alternative classes for this reason alone.¹⁵²

Put simply, Plaintiffs have not provided a viable method for calculating net profits derived from off-label prescriptions that were the result of any wrongdoing by Cephalon, much less shown how Plaintiffs expect to calculate any individual class member's damages for any proposed class. Under Rule 23, *Hydrogen Peroxide*, and well-settled law, Plaintiffs have failed to meet their burden and Plaintiffs' motion for class certification should be denied for this reason as well.

C. In Addition To The Individual Factual Questions, Class Certification Should Be Denied As Unmanageable Because Plaintiffs' Proposed Class Would Require The Court To Predict The Law Of All 51 Jurisdictions, Conduct A Choice-Of-Law Analysis, And Then Apply The Different Laws Of All States.

Although the Third Circuit has stated that the need to apply more than one law to the claims of class members does not *per se* "foreclose" certification,¹⁵³ the Third Circuit nonetheless requires that "class action movants must credibly demonstrate, through an 'extensive analysis' of state law

¹⁵⁰ Bradford Rep., Ex. 23, at ¶¶ 106-118.

¹⁵¹ Report of Christine Hammer ("Hammer Rep."), Ex. 25, at ¶¶ 50-76.

¹⁵² This promise to do something in the future is insufficient to sustain Plaintiffs' burden under Rule 23.

Hydrogen Peroxide, 552 F.3d at 318 ; *Somers v. Apple, Inc.*, 258 F.R.D. 354, 360-361 (N.D. Cal. 2009) (denying class certification and rejecting testimony of plaintiffs' expert largely because he "conceded that he has not yet developed a model" and offered nothing more than "proposals for accomplishing what the Court sees as a daunting task").

¹⁵³ In *Sullivan v. DB Investments, Inc.*, 667 F.3d 273 (3d Cir. 2011), the court approved a nationwide settlement class of indirect purchasers of diamonds. In passing, the court noted that "[a]s long as a sufficient constellation of common issues binds class members together, variations in the sources and application of applicable laws will not foreclose class certification." *Id.* at 302 (internal citations omitted). However, *Sullivan* in no way supports Plaintiffs' class certification motion or otherwise obviates Plaintiffs' burden to show, in detail, that variations between applicable laws are sufficiently manageable at a class trial, because *Sullivan* only addressed certification of a settlement class. Indeed, the court emphasized that because a settlement class does not involve a trial, "we simply need not inquire whether the varying state treatments of indirect purchaser damage claims at issue would present the type of 'insuperable obstacles' or 'intractable management problems' pertinent to certification of a litigation class." *Id.* at 304. By contrast, because Plaintiffs here propose a litigation class, this Court must conduct the detailed choice of law and manageability analysis that the *Sullivan* court held was irrelevant to a settlement class.

variances, that class certification does not present insuperable obstacles.” *Powers*, 328 F. App’x. at 124 (internal quotations and citations omitted). This is because the need to apply differing laws to separate claims by separate class members in the same action often makes a class trial unmanageable and inappropriate. *Id.* at 124 (“In diversity cases such as this, attempts to structure and certify nationwide classes involving plaintiffs in all fifty states often turn on whether the law of a single state or multiple states should be applied. Irreconcilable conflicts can be an impediment to certification . . .”). Indeed, “[i]f more than a few of the laws of the fifty states differ, the district judge would face an impossible task of instructing a jury on the relevant law.” *In re Am. Med Sys., Inc.*, 75 F.3d 1069, 1085 (6th Cir. 1996); *see also Klay*, 382 F.3d at 1261 (“it goes without saying that class certification is impossible where the fifty states truly establish a large number of different legal standards governing a particular claim.”); *In re Bridgestone/Firestone, Inc. Tires Prods. Liab. Litig.*, 288 F.3d 1012, 1018 (7th Cir. 2002) (“Because these claims must be adjudicated under the law of so many jurisdictions, a single nationwide class is not manageable.”).¹⁵⁴

Plaintiffs have not satisfied their burden; it is clear that materially different laws will apply to the claims of Plaintiffs’ proposed class. In determining what state’s laws apply to a particular class member’s claim, the Court must use the conflict of law principles of the state in which the Court sits – here, Pennsylvania. *See, e.g., Klaxon v. Stentor Electric Mfg. Co.*, 313 U.S. 487, 496 (1941); *Melville v. American Home Assur. Co.*, 584 F.2d 1306, 1308 (3d Cir. 1978). In a class action, the Court’s application of Pennsylvania choice of law rules must also comply with due process requirements. *See, e.g., Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 821 (1985).

Pennsylvania choice of law rules impose a two-step process to determine what laws apply. First, the Court must determine whether there is a true conflict between the unjust enrichment laws

¹⁵⁴ *See also Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1190 (9th Cir. 2001) (“The complexity of the trial would be further exacerbated to the extent that the laws of forty-eight states must be consulted to answer such questions.”); *Yarger v. ING Bank, Inc.*, 285 F.R.D. 308, 325 (D. Del. 2012) (holding that “material differences” between unjust enrichment laws “raise state law specific questions that defeat predominance”).

of interested states. *Id.* A true conflict exists “when the governmental interests of [multiple] jurisdictions would be impaired if their law were not applied.” *Lacey v. Cessna Aircraft Co.*, 932 F.2d 170, 187 (3d Cir. 1991); *see also Budget Rent-A-Car Sys., Inc. v. Chappell*, 407 F.3d 166, 170 (3d Cir. 2005). Because this Court is sitting in diversity jurisdiction, *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78-80 (1938), it therefore must make an “*Erie* prediction” (to the extent possible) about how each interested jurisdiction would define and apply its unjust enrichment law.

Second, if a conflict exists, “the court must then determine which state has the ‘greater interest in the application of its law.’” *Hammersmith v. TIG Ins. Co.*, 40 F.3d 220, 231 (3d Cir. 2007) (quoting *Cipolla v. Shaposka*, 439 Pa. 563, 267 A.2d 854, 856 (1970)). To do so, the Court must identify the contacts that each state has with the particular claim,¹⁵⁵ and then weigh these contacts along with that state’s interests and policies. *Id.*; *Powers*, 328 F. App’x. at 124-25.

As described below, the need to conduct complex choice-of-law determinations regarding the unjust enrichment law of each state itself renders class certification unmanageable. But even apart from that inquiry, a class trial would be unmanageable because the application of Pennsylvania’s choice of law analysis and principles of constitutional due process dictate the application of the law of each state where each TPP resides.

1. There Are Material Conflicts Between The Unjust Enrichment Laws Of All 50 States And The District Of Columbia.

Because Plaintiffs seek a nationwide class, the Court must evaluate how the substantive law of unjust enrichment is defined and applied in all 51 jurisdictions. It must do the same for Plaintiffs’ proposed alternative multi-state classes. There is a material conflict between unjust enrichment laws. Indeed, courts across the country repeatedly have held that a proposed multi-state

¹⁵⁵ As the Third Circuit has determined, these contacts require an evaluation of: (1) the place where the parties’ relationship was centered; (2) the state where defendants received the alleged benefit or enrichment; (3) the location where the act bestowing the enrichment or benefit was done; (4) the parties’ domicile, residence, place of business, and place of incorporation; and (5) the jurisdiction “where a physical thing . . . , which was substantially related to the enrichment, was situated at the time of the enrichment.” *Powers*, 328 F. App’x. at 126-27.

class under an unjust enrichment theory would be unmanageable because of differences in state law. See, e.g., *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 591 (9th Cir. 2012); *Cases Orlando Apts., Ltd. v. Fed. Nat'l Mortgage Assoc.*, 624 F.3d 185, 194-96 (5th Cir. 2010); 1 McLaughlin on Class Actions, § 5:46 (9th ed.) (“The majority view is that legal standards to prove an unjust enrichment claim sufficiently vary from state to state to preclude a finding of predominance”).¹⁵⁶

As demonstrated by the authorities cited in the attached appendices (and by way of example only), state unjust enrichment laws differ in at least the following material ways that are directly relevant to—and in some cases dispositive of—the issues in this case:

- **No Independent Cause of Action (Appendix A).** Several states do not recognize unjust enrichment as an independent tort cause of action—but, instead, as a measure of damages for an otherwise proven tort. Other states appear to be internally divided as to whether unjust enrichment can function as an independent cause of action. Still other states, like Pennsylvania, treat unjust enrichment claims that are based upon tort principles as a separate cause of action, but one that cannot survive independent of any other tort claim. By contrast, other states recognize unjust enrichment as a clearly defined autonomous cause of action that sounds in tort. As a result of these material differences, class members are not entitled to bring claims under the laws of certain states absent proving the elements of a separate tort.
- **Elements (Appendix B).** States also differ on the number and nature of elements that must be proven for an unjust enrichment claim. Even Plaintiffs themselves recognize that the elements for unjust enrichment differ markedly by state, and, for this very reason, have proposed alternative classes, although Plaintiffs’ attempt to “group” states ignores further relevant distinctions. (Pls. Br, at 28 (agreeing that there are at least four

¹⁵⁶ See also *Yarger*, 285 F.R.D. at 324-25; *True v. Conagra Foods, Inc.*, 2011 WL 176037, at *9 (W.D. Mo. Jan. 4, 2011); *Kottler v. Duetsche Bank*, 2010 WL 1221809, at *3-4 (S.D.N.Y. March 29, 2010); *Tyler v. Alltel Corp.*, 265 F.R.D. 415, 428-29 (E.D. Ark. 2010); *In re Aqua Dots Prods. Liab. Litig.*, 270 F.R.D. 377, 386 (N.D. Ill. 2010); *Cruz v. Lawson Software, Inc.*, 2010 WL 890038, at *6, 9-10 (D. Minn. Jan. 5, 2010); *Thompson v. Bayer Corp.*, 2009 WL 362982, at *4 (E.D. Ark. Feb. 12, 2009); *Spencer v. Hartford Fin. Serv. Group, Inc.*, 256 F.R.D. 284 (D. Conn. 2009); *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 461 (D.N.J. 2009); *Thompson v. Jiffy Lube Int'l, Inc.*, 250 F.R.D. 607, 626 (D. Kan. 2008); *In re Conagra Peanut Butter Prods. Liab. Litig.*, 251 F.R.D. 689, 697 (N.D. Ga. 2008); *Vulcan Golf, LLC v. Google Inc.*, 254 F.R.D. 521, 532 (N.D. Ill. 2008); *Siegel v. Shell Oil Co.*, No. 06 C 0035, 2008 WL 4378399, at *4 (N.D. Ill. Sept. 23, 2008); *In re Sears, Roebuck & Co. Tools Mktg. & Sales Practices Litigation*, MDL No. 1703, Nos. 05 C 4742 and 05 C 2623, 2007 WL 4287511, at *9 n. 7 (N.D. Ill. Dec. 4, 2007); *In re Sears, Roebuck & Co., In re Sears, Roebuck & Co. Tools Mktg. & Sales Litig.*, 2006 WL 3754823, at *1 (N.D. Ill. Dec. 18, 2006); *In re McDonald's French Fires Litig.*, 257 F.R.D. at 673; *Lilly v. Ford Motor Co.*, 2002 WL 507126, at *2 (N.D. Ill. Apr. 3, 2002); *Clay v. Am. Tobacco Co.*, 188 F.R.D. 483, 500-01 (S.D. Ill. 1999); *Lewis*, 2004 WL 1146692, at *12; *Gilman v. John Hancock Variable Life Ins Co.*, No. 00051, 2003 WL 23191098, *13 (Fla. Cir. Ct. Oct. 20, 2003); *Lectrodriver v. Seoulbank*, 77 Cal. App. 4th 723, 91 Cal. Rptr. 2d 881, 883 (Ca. Ct. App. 2000); *Ray Reilly's Tire Mart, Inc. v. F.P. Elnicki, Inc.*, 149 Vt. 37, 537 A.2d 994, 995 (Vt. 1987); *Dunlap v. Hinkle*, 173 W.Va. 423, 317 S.E. 2d 508, 512 n.2 (W.Va. 1984).

definitions of unjust enrichment across the country)). As a result of this variation, different proof is required to satisfy different unjust enrichment laws.

- ***Direct Conferral Of Benefit (Appendix C)***. Another material difference between state unjust enrichment laws is whether the plaintiff must directly confer a benefit on the defendant.¹⁵⁷ Many states impose a direct benefit requirement, while others do not. Still other states have yet to address the direct benefit requirement to pursue an unjust enrichment claim.¹⁵⁸ Because many class members, including the named Plaintiffs, never purchased Actiq directly from Cephalon and certainly never conferred a direct benefit on Cephalon,¹⁵⁹ they will not be able to bring claims in certain states.
- ***Different Conduct Requirements (Appendix D)***. There is also a conflict in the type of conduct needed to sustain a tort-based unjust enrichment claim, to the extent a particular jurisdiction even permits this type of unjust enrichment theory.¹⁶⁰ For example, some states require that the recipient of the benefit must have “engaged in some unconscionable conduct such as fraud, coercion or abuse of a confidential relationship.”¹⁶¹ Still other states require misconduct, but something less than actual fraud or dishonesty.
- ***Statute of Limitations (Appendix E)***. For Pennsylvania, there is a four-year limitation period for unjust enrichment claims.¹⁶² However, other states have a shorter three-year limitation period. This difference is particularly important, because Plaintiffs seek to certify a class that dates back to January 2002—more than five years prior to the filing of this case—and a 3-year limitation period will bar even more claims.
- ***Accrual of Limitations Period (Appendix F)***. There also are significant differences as to when an unjust enrichment claim begins to accrue. Thus, determining when each TPP’s claim started to accrue will vary by state law, and will require an individualized inquiry into the circumstances of each transaction by each TPP in that state, thereby rendering any class action unmanageable.
- ***No Adequate Remedy At Law (Appendix G)***. Numerous courts have acknowledged that states differ in whether unjust enrichment can survive even when there is an adequate remedy at law.¹⁶³ In states with a no-adequate-remedy-at-law requirement,

¹⁵⁷ See, e.g., *Kunzelmann*, 2013 WL 139913, at *10 (identifying conflict and cases).

¹⁵⁸ See, e.g., *Kunzelmann*, 2013 WL 139913, at *10.

¹⁵⁹ See Bradford Rep., Ex. 23, at ¶¶ 98-105; Schlegel Dep., Ex. 5, at 107:17-108:4, 177:3-178:11, 229:12-130:6; Newman Dep., Ex. 6, at 103:24-104:24, 105:10-23, 106:2-13, 177:6-17.

¹⁶⁰ See, e.g., *Kunzelmann*, 2013 WL 139913, at *10 (“The degree of wrongful conduct necessary to demonstrate unjust enrichment also varies between states.”); *Muehlbauer v. Gen. Motors Corp.*, 2009 WL 874511, at *5 (N.D. Ill. March 31, 2009) (identifying cases); *Clay*, 183 F.R.D. at 501 (“Some states do not specify the misconduct necessary to proceed, while others require that the misconduct include dishonesty or fraud.”).

¹⁶¹ See, e.g., *Welch v. Montgomery Eye Physicians, P.C.*, 891 So. 2d 837, 843 (Ala. 2004).

¹⁶² Pennsylvania has a borrowing statute that provides that “[t]he period of limitation applicable to a claim accruing outside this Commonwealth shall be either that provided or prescribed by the law of the place where the claim accrued or by the law of this Commonwealth, *whichever first bars the claim*.” 42 Pa. Cons. Stat. Ann. § 5521(b) (emphasis added). Thus, this Court would have to apply the shorter of 4 years or the limitation period under the law where the claim accrued. See *Brown v. Nationscredit Fin. Servs.*, 32 So. 3d 661, 662 n.1 (Fla. Dist. Ct. App. 2010); *Sevast v. Kakouras*, 915 A.2d 1147, 1153 (Pa. 2007).

¹⁶³ See, e.g., *Thompson*, 2009 WL 362982, at *6 (collecting cases).

each putative class member would be barred from bringing an unjust enrichment claim, since, as Plaintiffs themselves have pled, Cephalon allegedly violated the consumer fraud laws of all states. (Am. Compl., Ex. 2, at ¶¶ 110-122). At a minimum, an individualized analysis would be required to determine whether there is an available remedy at law in any state that imposes this requirement.

- **Defenses (Appendix H).** The availability and definition of certain relevant affirmative defenses to unjust enrichment principles also varies by state.¹⁶⁴ By way of example only, some states permit a defense of laches, but others do not.
- **Costing (Appendix I).** States use different methodologies for determining what costs can be deducted when performing a disgorgement or analogous “lost profit” analysis. For instance, some courts permit fixed costs to be deducted, while others do not.

In their brief, Plaintiffs argue that this Court can ignore these clear material differences and simply apply Pennsylvania law because, in ruling on summary judgment, the Court “ruled that there is no conflict between the laws of the 50 states on unjust enrichment” (Pls. Br., at 20). Plaintiffs’ argument does not withstand scrutiny. The Court’s summary judgment opinion did not determine what laws would apply to all claims by all putative class members, because it was simply not faced with that issue. In fact, the Court was not asked to make any choice of law determination because, for purposes of its summary judgment motion only, Cephalon conceded that there was no distinction between Indiana and Pennsylvania unjust enrichment law on the issues germane to that motion. (ECF No. 230-2, at 11 n.3); *In re Actiq Sales and Marketing Practices Litig.*, 790 F. Supp. 2d 313, 322 (E.D. Pa. 2011) (noting that “parties have not presented an issue concerning choice of law for these claims”). Thus, the Court’s opinion in no way eliminated Plaintiffs’ burden to show the absence of variation between the applicable laws of all 51 jurisdictions.

Plaintiffs also contend that the Court’s prior dicta concerning choice of law principles is now the law of the case. (Pls. Br., at 20-21). This is incorrect. The Third Circuit has repeatedly held that the law of the case doctrine does not apply to dicta. *See, e.g., Coca-Cola Bottling Co. of Shreveport, Inc. v. Coca-Cola Co.*, 988 F.2d 414, 429 (3d Cir. 1993). Moreover, the doctrine does

¹⁶⁴ *See, e.g., Yarger*, 285 F.R.D. at 325 (collecting cases).

not mandate that a court adhere to an earlier interlocutory order. *Schultz v. Onan Corp.*, 737 F.2d 339, 345 (3d Cir. 1984); *see also U.S. v. Eleven Vehicles*, 898 F. Supp. 1143, 1155 (E.D. Pa. 1995).

2. In Addition To The Many Material Conflicts, The Court Would Need To Make Numerous “*Erie* Guesses” Just To Determine Whether There Is A Conflict.

Apart from the task of applying multiple state laws in one class trial, the Court would face an unmanageable task in just determining what the law of each state is. It is well-recognized that “unjust enrichment is a tricky type of claim that can have varying interpretations even by courts within the same state, let alone among the fifty states.” *In re Sears, Roebuck & Co.*, 2006 WL 3754823 at *1 n. 3 (N.D. Ill. 2006). Thus, because this Court is sitting in diversity jurisdiction, the Court would have to make numerous “*Erie* predictions”—or, more accurately, “*Erie* guesses”—about what the elements of each unjust enrichment claim are under each state law, what proof is needed to succeed on such a claim, and how (if it all) each state’s top court would apply unjust enrichment principles in this tort context.

By way of example only, this Court would have to make a guess as to whether California and Mississippi would even recognize a cause of action for unjust enrichment (*see* Appendix A), much less how these jurisdictions would define and apply it. Likewise, the Court would need to determine whether some states would recognize an independent claim for unjust enrichment in the tort context, particularly when there is no underlying class-wide tort being asserted.¹⁶⁵ Courts routinely conclude that the need to confront such *Erie* guesses on novel or undeveloped state-law theories of liability weighs heavily against certification.¹⁶⁶ It also raises significant constitutional concerns.¹⁶⁷

¹⁶⁵ Indeed, the Third Circuit has affirmed the dismissal of an unjust enrichment claim under Pennsylvania law because while it “makes sense in cases involving a quasi-contract,” it does “not, as here, where plaintiffs are claiming damages for torts committed against them by [the] defendant.” *Boring v. Google, Inc.*, 362 F. Appx. 273, 282 (3d Cir. 2010).

¹⁶⁶ *See In re Bridgestone/Firestone, Inc. Tire Prods. Liab. Litig.*, 288 F.3d 1012, 1020 (7th Cir. 2002) (asking rhetorically, in determining that a class should not be certified, “[w]hat is the law of Michigan, or Arkansas, or Guam,

Plaintiffs primarily rely upon three cases to support their position that there is no material conflict between unjust enrichment laws (Pls. Br., at 21), but none is controlling and the reasoning in those cases has been rejected or distinguished by more recent and better-reasoned authority. For instance, the statement in *Powers v. Lycoming Engines*, 245 F.R.D. 226, 231 (E.D. Pa. 2007), that there are “few real differences” between the unjust enrichment laws of the various states has been rejected by numerous courts. *See, e.g., In re ConAgra Peanut Butter*, 251 F.R.D. at 697-98 (citing numerous cases). Indeed, the Third Circuit vacated the certification decision in *Powers* because the district court failed to conduct a proper choice of law analysis and incorrectly held that one law could apply to all putative class members’ claims. *Powers*, 328 F. App’x. at 121. On remand, Judge Savage denied class certification specifically *because of* the “multitude of legal standards that must be applied to each class member.” *Powers*, 272 F.R.D. 414, 426 (E.D. Pa. 2011).

The other two decisions upon which Plaintiffs rely, *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46 (D.N.J. 2009), and *In re Pennsylvania Baycol Third-Party Payor Litig.*, 2005 WL 852135 (Pa. Ct. Com. Pl. April 4, 2005), also offer no support. Neither court performed the analysis required by *Powers* and Pennsylvania choice-of-law principles concerning the material differences in unjust enrichment laws. *In Mercedes-Benz*, 257 F.R.D. at 48; *Baycol*, 2005 WL 852135, at *6-7.¹⁶⁸ And their logic is contrary to *Powers* and the vast majority of courts that have addressed this issue, and has been expressly rejected. *See, e.g., Tyler v. Alltel Corp.*, 265 F.R.D. 415, 422-23 (E.D. Ark. 2010) (rejecting *In re Mercedes-Benz* analysis and holding that unjust

as applied to this problem?”); *Castano*, 84 F.3d at 750 (“State courts can address the more novel of the plaintiffs’ claims, making the federal court’s *Erie* guesses less complicated. It is far more desirable to allow state courts to apply and develop their own law than to have a federal court apply ‘a kind of Esperanto [jury] instruction.’” (internal citations omitted)).

¹⁶⁷ *See In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1300 (7th Cir. 1995) (if one concludes that a novel claim “despite its controversiality would be decided identically in all 50 states and the District of Columbia, one wonders what the Supreme Court thought it was doing in the *Erie* case when it held that it was *unconstitutional* for federal courts in diversity cases to apply general common law rather than the common law of the state whose law would apply if the case were being tried in state rather than federal court.”).

¹⁶⁸ In fact, the *Baycol* Court acknowledged that “the law of unjust enrichment does vary from state to state,” *Baycol*, 2005 WL 852135, at *6, yet ignored these conflicts in holding that Pennsylvania law applied under the facts of that case.

enrichment claims are materially different); *Spencer v. Hartford Financial Services Group, Inc.*, 256 F.R.D. 284, 304 (D. Conn. 2009) (rejecting reliance upon *In re Pennsylvania Baycol* and holding that “none of these cases [cited by plaintiffs] provide a persuasive argument that the standards for unjust enrichment are sufficiently uniform from state to state to permit a finding of predominance”); *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 461 (D.N.J. 2009) (rejecting *In re Mercedes-Benz* analysis in finding that there is a material conflict between unjust enrichment law of New Jersey and California).¹⁶⁹

3. Under Pennsylvania Choice Of Law Rules, This Court Must Apply The Law Of The Jurisdiction Where Each TPP Resides Or Where The Purchase Took Place.

Because there are material conflicts between the laws of the 51 interested jurisdictions, it is necessary to proceed to the second step of Pennsylvania’s choice of law analysis: determining which state has the greater interest in having its law apply and to what issues. This requires a qualitative assessment—on an issue-by-issue basis—of each state law, the policies underlying each state law, and the contacts between the state and this action. *See, e.g., Powers*, 328 F. App’x. at 124-25; *Hammersmith*, 480 F.3d at 231. Here, the mere process of going through this qualitative analysis for all 51 jurisdictions (or even more than a few jurisdictions) makes Plaintiffs’ proposed class unmanageable. *See, e.g., Ritti v. U-haul Int’l Inc.*, No. 05-4182, 2006 WL 1117878, at *14 (E.D. Pa. April 26, 2006) (denying motion for class certification because “allowing this Class Action to proceed will require countless choice-of-law determinations and an unmanageable inquiry into the law governing the existence, terms, and breach of each contract, the availability of defenses

¹⁶⁹ Similarly, Plaintiffs also mistakenly rely upon other cases in which the defendants—unlike Cephalon here—either did not identify any specific differences in unjust enrichment and/or did not show that the differences in those laws would be material to the resolution of the specific claims in those cases. *See, e.g., Overka v. American Airlines, Inc.*, 265 F.R.D. 14, 20 (D. Mass. 2010) (although defendant “state[d] that unjust enrichment claims vary from state to state,” it “[did] not point to any particular difference”); *Keilholtz v. Lennox Hearth Prods.*, 268 F.R.D. 330, 341-42 (N.D. Cal. 2010) (“Defendants have not shown that the differences among the various state laws are material” in that they altered central issues or manner of proof in that case); *In re Abbott Labs. Norvir Antitrust Litig.*, 2007 WL 1689899, at *10 (N.D. Cal. June 11, 2007) (failing to analyze any specific differences in unjust enrichment laws in class action); *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 697 n.40 (S.D. Fla. 2004) (same).

to any breach, and the resulting damages for a vast number of the purported Class members”); *Emig v. Am. Tobacco Co.*, 184 F.R.D. 379, 393-94 (D. Kan. 1998) (denying class certification in part because the choice of law analysis alone would create manageability issues).

In conducting this very analysis for unjust enrichment claims brought by putative nationwide classes of TPPs, courts have refused to apply one law—and, instead, have applied the law where each payor resides and/or where the purchase took place. *See, e.g., In re Flonase Antitrust Litig.*, 815 F. Supp. 2d 867, 881-883 (E.D. Pa. 2011); *Sheet Metal Workers Local 441 v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 392 (E.D. Pa. 2010); *Lewis v. Bayer AG*, 2004 WL 1146692, at *12 (Pa. Ct. Com. Pls. Nov. 18, 2004).¹⁷⁰ The Third Circuit has also disapproved of the application of one law for unjust enrichment claims. In *Powers*, the Court vacated the district court’s class certification order, including its application of the law of the defendant’s home state (Pennsylvania) to a putative nationwide class, reasoning that “application of Pennsylvania’s choice-of-law principles may have indicated that the law of more than one state governs the parties’ dispute.” *Powers*, 328 F. App’x. at 127-128.

This is also consistent with what the Third Circuit has done in other contexts. *See, e.g., Nafar v. Hollywood Tanning Sys., Inc.*, 339 F. App’x. 216, 220-221 (3d Cir. Aug. 5, 2009) (vacating grant of class certification and reversing application of one state law’s consumer fraud statute to claims of all members of class in part because there were no “considerations that would appear to rebut the presumption that each prospective plaintiff’s home state has the most significant interest in litigating its resident’s claims”).

¹⁷⁰ Other courts have reached a similar conclusion—that the law of TPP’s home state must govern—based upon similar choice-of-law principles. *See, e.g., In re Sears, Roebuck & Co. Tools Mktg. & Sales Litig.*, 2006 WL 3754823, at *1 (N.D. Ill. Dec. 18, 2006) (laws of all 50 states apply in putative class action pursuant to most significant relationship test); *In re Grand Theft Auto*, 251 F.R.D. 139, 147-150 (S.D.N.Y. 2008) (reaching same conclusion under Pennsylvania choice of law rules and that of New York, California, Illinois, and Minnesota).

Because the parties' expectations are paramount in determining what law should apply, *see Powers*, 328 F. App'x. at 125, it is clear that the law of the jurisdiction where each TPP resides or where the purchase took place should govern each TPP's claim. The TPPs home state is the place where the TPP would have received communications (if any) from Cephalon, where it made the decision to reimburse, where it allegedly was injured by paying for purportedly inappropriate prescriptions of Actiq. For many TPPs, it is the place where its insureds received the prescriptions at issue, including all benefits from those prescriptions, and where each doctor made the decision to prescribe Actiq and was contacted, if at all, by Cephalon. In short, it is the place where, under Plaintiffs' theory of the case, each element of TPP's unjust enrichment claim occurred.

By contrast, Pennsylvania's contacts are limited to the place where Cephalon resides (for all class members other than those that are based in Pennsylvania). This contact is insufficient to apply Pennsylvania law to a multi-state, much less nation-wide, class of TPPs. *See, e.g., Powers*, 328 F. App'x. at 125; *True*, 2011 WL 176037, at *7-8. Indeed, while Pennsylvania has an interest in ensuring its residents are not unjustly enriched, this interest must cede to the interest of other states to ensure harm to its TPPs is redressed. This also complies with the parties' settled expectations. A California TPP, for instance, with no connection to Pennsylvania, could hardly have expected claims arising out of the payment for a medicine for a California insured, prescribed by a California doctor, following detailing by a Cephalon sales representative in California, to be governed by Pennsylvania law.

Ignoring this precedent, Plaintiffs rely exclusively upon one Pennsylvania state-court trial court decision (*Baycol*) to support their position that Pennsylvania law can apply to all claims by all class members across the country. (Pls. Br., at 22-23). This case, however, is distinguishable, because there were significant additional contacts with Pennsylvania germane to the unjust enrichment theory in that case. Unlike here, the Pennsylvania manufacturer in that case recalled

Baycol and then issued a refund policy from Pennsylvania pursuant to which it refunded the co-pay for unused prescriptions to individuals, but refused to refund payments by TPPs for unusable Baycol. Even more fundamentally, the choice-of-law analysis in *Baycol* was flawed for failing to evaluate, much less give proper weight to, the interests of other jurisdictions. *See Baycol*, 2005 WL 852135, at *5-6 (failing to evaluate the interests or contacts of any other jurisdiction). For this reason and others, its logic has been sharply rejected and its holding has not been followed by the Third Circuit or other courts. *See, e.g., Powers*, 328 F. App'x. at 125 (vacating class certification in part because choice of law analysis on “unjust enrichment issue lacked any discussion of the policies underlying the various states’ laws”); *Spencer*, 256 F.R.D. at 305 (disagreeing with choice of law conclusion in denying class certification on unjust enrichment claim); *Wyeth*, 42 So. 3d at 1227 n.8 (rejecting and distinguishing *Baycol* analysis in affirming denial of class certification on unjust enrichment claim by TPP against pharmaceutical company).

4. Plaintiffs’ Effort To Sidestep These Material Conflicts And Manageability Problems Through Alternative Multi-State Classes Also Fails For The Same Reasons.

Plaintiffs seek to “overcome” these state law differences and manageability problems by proposing an alternative in which they roughly group select states together based upon how Plaintiffs say those states define their unjust enrichment laws. (Pls. Br., at 26-30). Plaintiffs seek certification of two of these groups—their so-called “Restatement” Alternative Class (which consists of all TPPs in 12 states) and their “Appreciation” Alternative Class (which consists of all TPPs in 21 states). (*Id.*). These proposed alternative groups are only superficial groupings that neither account for key differences in how each state applies its unjust enrichment law nor eliminate the Court’s burden to make accurate “*Erie*” predictions. They therefore fail to satisfy Plaintiffs’ burden of showing that a class action involving multiple state laws would be manageable.

As a threshold matter, Plaintiffs' superficial clustering of state laws is inaccurate. By way of example only, Plaintiffs contend that only four states (but not those in the "Restatement" Alternative Class or "Appreciation" Alternative Class) "require a 'connection' between the impoverishment of a plaintiff and the enrichment of a defendant as a part of the cause of action." (Pls. Br., at 28). But that is not true. Nearly all states require a causal connection between the plaintiffs' alleged loss and the defendants' alleged gain, although states formulate this requirement differently.¹⁷¹ And principles of Article III standing also impose a causation requirement, since a TPP cannot bring a claim against Cephalon unless it can demonstrate that Cephalon's conduct caused that TPP's injury.¹⁷² Plaintiffs' attempt to eliminate this causation requirement through their proposed alternative classes fails as a matter of law.

Plaintiffs have not demonstrated (and cannot demonstrate) that there are no material differences between the unjust enrichment laws of the states that have been grouped together. For instance, Plaintiffs' charts of the "Restatement" Alternative Class and the "Appreciation" Alternative Class (Exhibits 12-13 to Pls. Br.) fail to address core conflicts (identified above), such as whether an unjust enrichment claim can exist on its own in the tort setting, whether a direct relationship is required between the parties, whether there is a no-adequate-remedy-of-law

¹⁷¹ See, e.g., *Serv. Employees Int'l Union Health & Welfare Fund v. Philip Morris Inc.*, 249 F.3d 1068, 1076 n.6 (D.C. Cir. 2001) (finding that plaintiff's unjust enrichment claim under District of Columbia law would fail for lack of proximate cause); *Employer Teamsters-Local Nos. 175/505 Health & Welfare Trust Fund*, No. 12-0587, at *1 (granting motion to dismiss unjust enrichment claim under West Virginia law for failure to sufficiently plead proximate causation); *Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 324 (D. Mass. 2005) (to prove a claim for unjust enrichment under Massachusetts law, "a party must show: (1) an enrichment; (2) an impoverishment; (3) a relation between the enrichment and the impoverishment; (4) an absence of justification and (5) the absence of a remedy provided by law."); *U.S. Minerals & Min., Inc. v. Licensed Processors, Ltd.*, 551 N.E.2d 661, 665 (Ill. App. Ct. 1990) (whatever profits the defendant may have gained do not constitute unjust enrichment, unless there was some showing that the profit resulted from unlawful or improper conduct of the defendant); *Uzyel v. Kadisha*, 116 Cal. Rptr. 3d 244, 266 (Cal. App. Ct. 2010) (noting that unjust enrichment involves "questions of causation and remoteness, that is, how far to follow a chain of causation before deciding that the causal connection is too attenuated to justify a recovery"); *Southard v. Visa U.S.A. Inc.*, 734 N.W.2d 192, 199-200 (Iowa 2007) (claims for unjust enrichment are "subject to the common-law rule that bars recovery for remote injuries").

¹⁷² *In re Schering Plough Corp.*, 678 F.3d at 246-47 (applying Article III requirements to dismiss claims by TPPs, based upon allegations of off-label promotion, because TPPs failed to allege "connection between Local 331's injury-in-fact and Schering's allegedly illegal marketing or bribery schemes"). Furthermore, "no class may be certified that contains members lacking Article III standing." *Denney v. Deutsche Bank AG*, 443 F.3d 253, 264 (2d Cir. 2006).

requirement, statute of limitations distinctions, and differences in what defenses are permitted and how they apply. As detailed in the attached Appendices, the laws within Plaintiffs' proposed alternative classes differ widely on these issues.¹⁷³ For these reasons, Plaintiffs' charts fail to satisfy Plaintiffs' burden of demonstrating the absence of unmanageable material conflicts within the so-called "Restatement" and "Appreciation" Alternative Classes.¹⁷⁴

Not surprisingly, Plaintiffs' effort to circumvent material conflicts by grouping state unjust enrichment laws based exclusively on their definition (or elements) has been repeatedly rejected.¹⁷⁵ In *Kunzelman*, the court recently rejected Plaintiffs' argument that "27 states were substantially similar in their law of unjust enrichment and that only six of those states required a plaintiff to show it had conferred a direct benefit." *Kunzelman*, 2013 WL 139913, at *10-11. Because Plaintiffs failed to show the absence of variation among the laws of the states for which certification was sought, the court denied the Plaintiffs' class motion. *Id.*

Put simply, the need to apply the varying laws of all 50 states—or even 33 states (as proposed by Plaintiffs' alternative "Restatement" and "Appreciation" classes)—makes nationwide class certification unmanageable and inappropriate. *See, e.g., Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 618 (3d Cir. 1996) (decertifying class because legal and factual differences in the plaintiffs' claims "when exponentially magnified by choice of law considerations, eclipse any

¹⁷³ For instance, Colorado has a three-year limitation period, while Pennsylvania has a 4-year limitation period, and the accrual rules may be different. (*See* Appendix E). Florida requires the plaintiff to directly confer a benefit onto the defendant, but Tennessee does not. (*See* Appendix C). Hawaii does not permit a plaintiff to recover if it has an adequate remedy at law, but Illinois may in some circumstances (*See* Appendix G). Illinois does not permit a party to assert a laches defense against an unjust enrichment claim, but Connecticut does. (*See* Appendix H).

¹⁷⁴ *See also In re Sears, Roebuck & Co. Tools Marketing & Sales Practices Litig.*, No. 05 C 4742, 2006 WL 3754823, at *1 n.3 (N.D. Ill. Dec. 18, 2006).

¹⁷⁵ *See also Yarger*, 285 F.R.D. at 325 ("Plaintiffs have failed to meet their burden of establishing that there is not a material variation among the unjust enrichment laws of the sixteen states, as they have merely 'provid[ed] excerpts of the elements of the [sixteen] states' unjust enrichment claims as proof of their similarity, [and they] notably fail to discuss the states' laws in detail or address the concerns raised by numerous other courts that have found significant differences in the laws."); *Muehlbauer*, 2009 WL 874511, at *5 (rejecting plaintiffs' attempt to group unjust enrichment claims "into one of three categories based on the general elements needed to prove unjust enrichment in that state," because chart lacked "discussion of the merits of the listed cases or variations in the requirements necessary to prove each element or the affirmative defenses" for unjust enrichment).

common issues in this case”). Just the jury instructions alone would present be an insurmountable obstacle to any such class trial. *In re Am. Med. Sys., Inc.*, 75 F.3d at 1085 (“[i]f more than a few of the laws of the fifty states differ, the district judge would face an impossible task of instructing a jury on the relevant law”).¹⁷⁶ Accordingly, Plaintiffs’ motion should be denied.

D. In Addition To Failing To Satisfy The Commonality, Predominance, And Manageability Requirements, Plaintiffs Cannot Satisfy The Remaining Requirements For Class Certification.

1. Plaintiffs Are Not Adequate Class Representatives.

Cephalon does not challenge the adequacy of class counsel. However, Plaintiffs clearly are not adequate class representatives. To be an adequate class representative, a plaintiff “must not have interests antagonistic to those of the class.” *Wetzel v. Liberty Mut. Ins. Co.*, 508 F.2d 239, 247 (3d Cir. 1975). It is well-settled that a class representative is not an adequate representative when the class representative abandons particular remedies to the detriment of the class. *See, e.g., Nafar*, 339 F. App’x. at 223-24 (vacating class certification in part because district court failed to properly analyze whether named plaintiffs’ decision to “disavow[] claims for personal injury, arising from the same conduct challenged in this case, would adversely affect members of the class”); *Western States Wholesale, Inc. v. Synthetic Indus., Inc.*, 206 F.R.D. 271, 277 (C.D. Cal. 2002); *In re Methyl Tertiary Butyl Ether (“MTBE”) Prods. Liab. Lit.*, 209 F.R.D. 323, 340 (S.D.N.Y. 2002). Here, Plaintiffs cannot satisfy the adequacy requirement of Rule 23(a) because they have abandoned putative class members’ statutory consumer fraud claims. This creates a material conflict with the putative class.

First, Plaintiffs have abandoned class-wide relief in the form of each TPP’s actual damages (if any). In addition, because Plaintiffs have offered no method of apportioning profits by class

¹⁷⁶ See also *Klay*, 382 F.3d at 1261, *abrogated in part on other grounds by Bridge v. Phoenix Bond & Indemn. Co.*, 553 U.S. 639 (2008); *Rhone-Poulenc*, 51 F.3d at 1300; *Castano*, 84 F.3d at 741; *Kunzelmann*, 2013 WL 139133, at *11; *In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 174 F.R.D. 332, 349 (D.N.J. 1997); *Vioxx*, 239 F.R.D. at 460-61; *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555, 563-65 (E.D. Ark. 2005); *Chin v. Chrysler Corp.*, 182 F.R.D. 448, 461-62 (D.N.J. 1998); *In re Stucco Litig.*, 175 F.R.D. 210, 215-17 (E.D.N.C. 1997).

member, there will be significant conflicts between putative class members about what they are entitled to recover through a disgorgement allocation. *See, e.g., Western States Wholesale, Inc.*, 271 F.R.D. at 277 (finding adequacy not met because named plaintiff “has not put forth a method of apportioning SI’s profits or lost sales among the class members” and because, as a result, “[a]ny claim Western States makes to SI’s wrongful profits or any lost sales will necessarily diminish the amount of profits or lost sales another class member can recover”).

Second, if a class is certified, *res judicata* will bar the abandoned statutory consumer fraud claims or any other claims, and with them, additional remedies available under those theories, such as attorneys’ fees and longer limitation periods. *See Nafar*, 339 F. App’x. at 224-25; *Pearl v. Allied Corp.*, 102 F.R.D. 921, 924 (E.D. Pa. 1984) (“class members whose claims would be abandoned by the plaintiffs may find themselves precluded by the doctrine of *res judicata* from asserting those claims in subsequent actions ...[and] [f]or this reason the plaintiffs cannot properly serve as class representatives”).¹⁷⁷ Thus, Plaintiffs are inadequate class representatives.

2. Plaintiffs’ Claims Are Not Typical.

The Third Circuit has held that “[t]ypicality entails an inquiry into whether the named [plaintiff’s] individual circumstances are markedly different or the legal theory upon which the claims are based differs from that upon which the claims of the other class members will perforce be based.” *Hassine v. Jeffes*, 846 F.2d 169, 177 (3d Cir. 1988). Here, Plaintiffs’ claims are not typical because:

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¹⁷⁷ Additionally, Pennsylvania law imposes a 6-year statute of limitations for consumer fraud claims, *Gabriel v. O’Hara*, 534 A.2d 488, 494 (Pa. Super. Ct. 1987), but only a 4-year limitation period for unjust enrichment claims. Likewise, attorneys’ fees are available as a matter of statutory right for a consumer fraud claim under Pennsylvania law, but not for an unjust enrichment claim. *See* 73 Pa. Cons. Stat. Ann. § 201-9.2 (“The court may award to the plaintiff, in addition to other relief provided in this section, costs and reasonable attorney fees.”).

• [REDACTED]

• [REDACTED]

Because Plaintiffs' factual circumstances—and hence their equitable claim for disgorgement of Cephalon's profits—are not typical of those of other putative class members, Plaintiffs cannot satisfy Rule 23's typicality requirement.

3. Class Treatment Is Not A Superior Method To Resolve These Claims.

Plaintiffs also cannot demonstrate “that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” Fed. R. Civ. P. 23(b)(3); *Georgine*, 83 F.3d at 625-26. Here, putative class members have an incentive to bring their own actions for damages. ICWF contends that it paid approximately [REDACTED] for off-label Actiq prescriptions, and PTC contends that it paid approximately [REDACTED]. With such amounts at stake, putative class members have every incentive to bring individual lawsuits—and, unlike Plaintiffs, to seek actual damages (rather than disgorgement) under statutes that permit attorneys' fees to the prevailing party. As such, a class action is unnecessary and not the superior method of resolving the controversy. *See, e.g., Amchem Prods. v. Windsor*, 521 U.S. 591, 617 (1997); *Jackson*, 260 F.R.D. 168, 197-98 (E.D. Pa. 2009).¹⁸²

¹⁷⁸ See SOF, Ex. 1, at ¶¶ 47-48, 89-91.

¹⁷⁹ Am. Compl., Ex. 2, at ¶ 61.

¹⁸⁰ See SOF, Ex. 1, at ¶¶ 67-70; Bradford Rep., Ex. 23, at ¶¶ 51-53.

¹⁸¹ See SOF, Ex. 1, at ¶¶ 118-120.

¹⁸² Other courts have reached the same result. *See, e.g., Pipefitters Local 636 Ins. Fund v. Blue Cross Blue Shield*, 654 F.3d 618, 632 (6th Cir. 2011) (reversing class certification in a case seeking \$280,000 per class member, because such sums “are not the types of awards that would preclude individual class members from seeking relief through litigation”); *Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1191 (9th Cir. 2001) (superiority lacking where claims exceeded \$50,000); *Estate of Felts v. Genworth Life Ins. Co.*, 250 F.R.D. 512, 526 (W.D. Wash. 2008) (claims averaging \$50,000 “mean that there is substantial incentive for an individual” to bring individual suit); *Ansari v.*

4. Plaintiffs' Proposed Class Includes Members Who Have Suffered No Injury, As Required By Article III And Third Circuit Precedent.

Finally, courts have denied certification where the putative class “contains members lacking Article III standing,” such as members who never suffered any injury traceable to the defendants’ actions. *Penney v. Deutsche Bank AG*, 443 F.3d 253, 264 (2d Cir. 2006) (affirming the denial of a plaintiff class because the definition of the class was “so amorphous and diverse” that it was not “reasonably clear that the proposed class members have all suffered a constitutional or statutory violation warranting some relief”).¹⁸³

Here, Plaintiffs’ putative class is overbroad because it includes any TPP that paid for any off-label prescriptions of Actiq between 2002 and 2006, regardless of whether: (a) Cephalon did anything improper to cause the off-label prescription of Actiq to be written; (b) the payor reimbursed for off-label prescriptions of Actiq with full knowledge that it was doing so; (c) the off-label prescription was medically appropriate for the patient; (d) the payor received full value for the off-label prescriptions of Actiq; and (e) Actiq enabled the payor to avoid more expensive alternatives and/or the payor was able to cover its costs through its premiums. To certify such a class would be to allow Plaintiffs to pursue claims against TPPs who never suffered any injury because of any alleged misconduct by Cephalon.

V. CONCLUSION

For the preceding reasons, Plaintiffs’ motion for class certification should be denied with prejudice.

New York Univ., 179 F.R.D. 112, 116 (S.D.N.Y. 1998) (“A potential award of around \$90,000 is hardly the type of de minimis recovery that would discourage individual class members from joining [this] suit or from filing suits in their own behalf.”).

¹⁸³ See also *Owen v. Regence Bluecross Blueshield*, 388 F.Supp.2d 1318, 1334 (D. Utah 2005) (“[T]he proposed definition of the class is overbroad because many of the proposed class members have suffered no damages”); *Presbyterian Church of Sudan v. Talisman Energy, Inc.*, 244 F. Supp. 2d 289, 334 (S.D.N.Y. 2003) (noting that “each member of the class must have standing with respect to injuries suffered as a result of defendants’ actions”); *Zapka v. Coca-Cola Co.*, 2000 WL 1644539, at *3 (N.D. Ill. Oct. 27, 2000) (holding class definition improper where it included individuals who were not harmed).

Dated: March 20, 2013

Respectfully submitted,



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CERTIFICATE OF SERVICE

I, Jeremy A. Menkowitz, hereby certify that on March 20, 2013, a true and correct copy of Cephalon's Memorandum Of Law In Opposition To Plaintiffs' Motion For Class Certification, the Declaration of Jeremy Menkowitz in Support of Cephalon's Memorandum Of Law In Opposition To Plaintiffs' Motion For Class Certification, and all exhibits thereto, was served via electronic mail upon all counsel of record.

Respectfully,

DATED: March 20, 2013

s/Jeremy A. Menkowitz

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APPENDIX A:
STATES DIFFER AS TO WHETHER
UNJUST ENRICHMENT IS AN INDEPENDENT TORT

A. Examples Of States Where Unjust Enrichment Is Not An Independent Tort-Based Cause Of Action

- Kentucky: *Cheatham v. Paisano Publ'ns, Inc.*, 891 F. Supp. 381, 387 n.7 (W.D. Ky. 1995) (finding that where underlying claim is a tort, unjust enrichment “merely forms a measure of damages” and “is not a separate cause of action”)
- Florida: *State v. Tenet Healthcare Corp.*, 420 F. Supp. 2d 1288, 1309 (S.D. Fla. 2005) (dismissing unjust enrichment claim under Florida law because “Plaintiffs cannot base an unjust enrichment claim on alleged wrongdoing for which an independent basis for recovery exists” and because “[a]s soon as a claimant relies on a wrong to supply the unjust factor . . . ‘the right on which [the plaintiff] relies arises from that wrong, not from unjust enrichment.’”)
- Massachusetts: *Lopes v. Commonwealth*, 811 N.E.2d 501, 509 (Mass. 2004) (“[T]he plaintiffs’ claim of unjust enrichment does not state a separate cause of action, but a theory of recovery.”)
- New Hampshire: *Gen. Insulation Co. v. Eckman Constr.*, 992 A.2d 613, 621 (N.H. 2010) (finding that “unjust enrichment generally does not form an independent basis for a cause of action”)
- Texas: *Richardson Hospital Authority v. Duru*, 387 S.W.3d 109, 114 (Tex. App. Ct. 2012) (“This Court has held that unjust enrichment is not an independent cause of action.”)

B. Examples Of States With Conflicting Authority As To Whether Unjust Enrichment Is An Independent Tort Cause Of Action

- California: *Compare Melchior v. New Line Prods., Inc.*, 106 Cal. App. 4th 779, 131 Cal. Rptr. 2d 347, 357 (Cal. Ct. App. 2003) (“[T]here is no cause of action in California for unjust enrichment.”), *with Lectordryer v. SeoulBank*, 77 Cal. App. 4th 723, 91 Cal. Rptr. 2d 881, 883–84 (Cal. Ct. App. 2000) (permitting an unjust enrichment claim to stand);
- Mississippi: *Compare Blades v. Countrywide Home Loans, Inc.*, Civil Action No. 1:06CV1000–LG–JMR, 2007 WL 2746678, at *5 (S.D. Miss. Sept. 17, 2007) (holding that Mississippi courts recognize the existence of an unjust enrichment theory of recovery), *with Cole v. Chevron USA*, 554 F. Supp. 2d 655, 671–73 (S.D. Miss. 2007) (“Under Mississippi law, unjust enrichment is not an independent theory of recovery.”).

C. Examples Of States That Treat Unjust Enrichment Claims That Are Based Upon Tort Principles As A Separate Cause Of Action, But One That Requires An Underlying Tort Claim

- Pennsylvania: *Boring v. Google, Inc.*, 362 F. App'x 273, 282 (3d Cir. 2010) (affirming dismissal of unjust enrichment claim under Pennsylvania law because while it “makes sense in cases involving a quasi-contract,” it does “not, as here, where plaintiffs are claiming damages for torts committed against them by [the] defendant” and holding that “[b]ecause we find that the Borings stated a claim for trespass . . . and thus survived a 12(b)(6) motion to dismiss as to that claim, we need not address whether unjust enrichment is a stand-alone tort under Pennsylvania law”) and *Zafarana v. Pfizer*, 724 F. Supp. 2d 545, 560–61 (E.D. Pa. 2010) (finding that Pennsylvania does not recognize “an action for a stand-alone tort of unjust enrichment”)
- New Jersey: *Blystra v. Fiber Tech Group, Inc.*, 407 F. Supp. 2d 636, 644 n.11 (D.N.J. 2005) (treating plaintiffs’ unjust enrichment claims as “subsumed by their other tort claims, and not as an independent cause of action”); *Castro v. NYT Television*, 851 A.2d 88, 98 (N.J. Super. Ct. App. Div. 2004) (holding that “the role of unjust enrichment in the law of torts is limited for the most part to its use as a justification for other torts such as fraud or conversion”)
- Alaska: *Alaska Sales and Serv., Inc. v. Millet*, 735 P.2d 743, 746 (Alaska 1987) (“[U]njust enrichment is not in and of itself a theory of recovery. Rather, it is a prerequisite for the enforcement of the doctrine of restitution; that is, if there is no unjust enrichment, there is no basis for restitution. Restitution, in turn, is not a ‘cause of action’ but rather a remedy for various causes of actions.”)
- Illinois: *Lewis v. Lead Indus. Ass’n*, 793 N.E.2d 869, 877 (Ill. App. Ct. 2003) (internal citations omitted) (“However, as the defendants correctly argue, the term ‘unjust enrichment’ is not descriptive of conduct which, standing alone, will justify an action for recovery. In order for a cause of action for unjust enrichment to exist, there must be some independent basis which establishes a duty on the part of the defendant to act and the defendant must have failed to abide by that duty.”)

D. Examples Of States That Treat Unjust Enrichment Claims As An Autonomous Cause Of Action

- Colorado: *Lewis v. Lewis*, 189 P.3d 1134, 1141 (Colo. 2008) (recognizing a free-standing claim for unjust enrichment)
- Maine: *Fed. Ins. Co. v. Me. Yankee Atomic Power Co.*, 183 F. Supp. 2d 76, 86 n.16 (D. Me. 2001) (“[I]t is often said that unjust enrichment, along with tort and contract, is a distinct source of available civil liability.”)
- Nebraska: *City of Scottsbluff v. Waste Connections, Inc.*, 809 N.W.2d 725 (Neb. 2011) (finding that unjust enrichment constitutes “an independent basis of liability in common-law legal systems—comparable in this respect to a liability in contract or tort”)
- New Mexico: *Starko, Inc. v. Presbyterian Health Plan, Inc.*, 276 P.3d 252, 277 (N.M. Ct. App. 2011) (declaring that “unjust enrichment constitutes an independent basis for liability” (quoting *Hydro Conduit Corp. v. Kemble*, 793 P.2d 855, 860 (N.M. 1990))
- Rhode Island: *Dellagrotta v. Dellagrotta*, 873 A.2d 101, 113 (R.I. 2005) (finding that unjust enrichment “is not simply a remedy in contract and tort but can stand alone as a cause of action in its own right”)

APPENDIX B:

STATES DIFFER AS TO THE NUMBER AND TYPE OF ELEMENTS FOR UNJUST ENRICHMENT CLAIMS

A. Examples Of States With No Discrete Constituent Elements For An Unjust Enrichment Claim

- Vermont: *Ray Reilly's Tire Mart, Inc. v. F.P. Elnicki, Inc.*, 537 A.2d 994, 995 (Vt. 1987) ("The standard to be used in deciding a claim for unjust enrichment is "whether [defendant] received a benefit for which plaintiff should be compensated The law implies a promise to pay when a party receives a benefit and the retention of the benefit would be inequitable" (internal citations and quotations omitted))
- West Virginia: *Dunlap v. Hinkle*, 317 S.E.2d 508, 512 n.2 (W. Va. 1984) ("Unjust enrichment of a person occurs when he has and retains money or benefits which in justice and equity belong to another The benefit may be an interest in money, land, chattels, or choses in action; beneficial services conferred; satisfaction of a debt or duty owed by him; or anything which adds to his security or advantage." (quotations omitted))

B. Examples Of States With Five Elements For An Unjust Enrichment Claim

- Arizona: *Cnty. Guardian Bank v. Hamlin*, 898 P.2d 1005, 1008 (Ariz. Ct. App. 1995) ("In Arizona, five elements must be proved to make a case of unjust enrichment: (1) an enrichment; (2) an impoverishment; (3) a connection between the enrichment and the impoverishment; (4) absence of justification for the enrichment and the impoverishment and (5) an absence of a remedy provided by law.")
- Delaware: *Jackson Nat'l Life Ins. Co. v. Kennedy*, 741 A.2d 377, 393-94 (Del. Ch. 1999) ("The elements of unjust enrichment are: (1) an enrichment, (2) an impoverishment, (3) a relation between the enrichment and impoverishment, (4) the absence of justification and (5) the absence of a remedy provided by law.")
- Louisiana: *Troxler v. Breaux*, 105 So. 3d 944, 948 (La. Ct. App. 2012) ("Under Louisiana law, the requisite elements of a claim for unjust enrichment are: (1) an enrichment; (2) an impoverishment; (3) a connection between the enrichment and the impoverishment; (4) an absence of justification or cause for the enrichment and impoverishment; and (5) no other available remedy at law.")

C. Examples of States With Conflicting Four-Element Standards For An Unjust Enrichment Claim, Including An Exhaustion Of Remedies Requirement

- Wyoming: *Schlenger v. McGhee*, 268 P.3d 264, 272 (Wyo. 2012) (“In Wyoming, the elements of unjust enrichment are: 1) valuable services were rendered; 2) to the party to be charged; 3) which services were accepted, used and enjoyed by the charged party; and 4) under circumstances that reasonably notified the party being charged that the other party would expect payment for the services”)
- Tennessee: *Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 525–26 (Tenn. 2005) (“The elements of an unjust enrichment claim are: 1) ‘[a] benefit conferred upon the defendant by the plaintiff’; 2) ‘appreciation by the defendant of such benefit’; and 3) ‘acceptance of such benefit under such circumstances that it would be inequitable for him to retain the benefit without payment of the value thereof.’ . . . The plaintiff must further demonstrate that he or she has exhausted all remedies against the person with whom the plaintiff enjoyed privity of contract.”)

D. Examples Of States With Varying Three-Element Standards For An Unjust Enrichment Claim

- Colorado: *Robinson v. Colo. State Lottery Div.*, 179 P.3d 998, 1007 (Colo. 2008) (“The test for recovery under an unjust enrichment theory requires a showing that (1) at plaintiff’s expense (2) defendant received a benefit (3) under circumstances that would make it unjust for defendant to retain the benefit without paying.” (citing *DCB Constr. Co., Inc. v. Cent. City Dev. Co.*, 965 P.2d 115, 119–20 (Colo. 1998)))
- Connecticut: *Town of New Hartford v. Conn. Res. Recovery Auth.*, 970 A.2d 592, 609 (Conn. 2009) (“Plaintiffs seeking recovery for unjust enrichment must prove (1) that the defendants were benefited, (2) that the defendants unjustly did not pay the plaintiffs for the benefits, and (3) that the failure of payment was to the plaintiffs’ detriment.” (citations and internal quotation marks omitted.))
- Illinois: *Yugoslav-Am. Cultural Ctr. v. Parkway Bank & Trust Co.*, 763 N.E.2d 360, 367 (Ill. Ct. App. 2001) (“Recovery under an unjust enrichment theory requires a showing that the defendant has voluntarily accepted a benefit that it would be inequitable for him to retain without payment since the law implies a promise to pay compensation when value of the services are knowingly accepted.” (citing *Knaus v. Dennler*, 525 N.E.2d 207 (Ill Ct. App. 1988)))
- Massachusetts: *Patel v. Emerald P’ship, Ltd.*, Civil Action No. 00-1033-H, 2009 WL 1058356, at *24 (Mass. Sup. Ct. Apr. 9, 2009) (“Three elements must be established in order that a plaintiff may establish a claim based on unjust enrichment. These elements are: 1) A benefit conferred upon the defendant by the plaintiff; 2) An appreciation or knowledge by the defendant of the benefit; and 3) The acceptance or retention by the defendant of the benefit under such circumstances as to make it inequitable for the defendant to retain the benefit without payment of its value.”)

- New Jersey: *VRG Corp v. GKN Realty Corp.*, 641 A.2d 519, 526 (N.J. 1994) (defining elements to unjust enrichment claim as: (1) benefit conferred; (2) plaintiff expected remuneration from defendant; (3) retention of such benefit without payment would be unjust in that failure of remuneration enriched defendant beyond its rights.)

F. Examples Of States Where Courts Have Taken Conflicting View As To The Number And Nature Of Elements For An Unjust Enrichment Claim

- North Carolina: Compare *Jackson v. Carolina Hardwood Co.*, 120 N.C. App. 870, 872, 463 S.E.2d 571, 573 (N.C. Ct. App. 1995) (“In order to state a claim for unjust enrichment, the plaintiffs allegations must set forth that a benefit was conferred on the defendant, that the defendant accepted the benefit, and that the benefit was not gratuitous.”), with *Patriot Performance Materials, Inc. v. Powell*, No. 12 CVS 814, 2013 WL 601098, at *1 (N.C. Super. Ct. Feb. 13, 2013) (“In order to prevail on a claim for unjust enrichment, a plaintiff must show that (1) it conferred a benefit on the other party; (2) the benefit was not conferred officiously; (3) the benefit was not gratuitous; (4) the benefit is measurable; and (5) the defendant consciously accepted the benefit.”).

APPENDIX C:

STATES DIFFER AS TO WHETHER A BENEFIT MUST BE DIRECTLY CONFERRED

A. Examples of States That Require A Benefit To Be Directly Conferred By The Plaintiff

- Florida: *St. Petersburg v. Dayco Prods., Inc.*, No. 06-20953-CIV, 2008 WL 5428172, at *8 (S.D. Fla. Dec. 30, 2008) (granting summary judgment because plaintiffs had *indirectly* purchased the defendants' products from a distributor and, as such, never dealt directly with the defendants); *Am. Safety Ins. Serv. v. Griggs*, 959 So. 2d 322, 331 (Fla. 5th DCA 2007) (dismissing unjust enrichment claim where defendant was overpaid by third parties and explaining that the benefit must be "directly conferred" on the defendant)
- Kansas: *Spires v. Hosp. Corp. of Am.*, 289 F. App'x 269, 273 (10th Cir. 2008) ("Plaintiffs have pointed to nothing in Kansas law that supports an indirect unjust enrichment claim")
- Maine: *Rivers v. Amato*, No. CIV. A. CV-00-131, 2001 WL 1736498, at *4 (Me. Super. June 22, 2001) (granting summary judgment on Maine unjust enrichment claim where plaintiff did not allege that he "directly . . . conferred a benefit on [d]efendants")
- New Jersey: *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 711 (D.N.J. 2011) (dismissing unjust enrichment claim under New Jersey law because there must be a direct relationship and "[w]hen consumers purchase a product from a third party, they confer a benefit on that third party, not on the manufacturer"); *Cooper v. Samsung Elecs. Am., Inc.*, Civil Action No. 07-3853, 2008 WL 4513924, at *10 (D.N.J. Sept. 30, 2008) (dismissing unjust enrichment claim under New Jersey law because "although Cooper alleges that Samsung was unjustly enriched through the purchase of the television, there was no relationship conferring any direct benefit on Samsung through Cooper's purchase, as the purchase was through a retailer, Ultimate Electronics"), *aff'd*, No. 08-4736, 2010 WL 1220946 (3rd Cir. Mar. 30, 2010)
- New York: *In re Bayou Hedge Funds Investment Litig.*, 472 F. Supp. 2d 528, 532 (S.D.N.Y. 2007) ("The benefit must be 'specific' and 'direct' in order to support an unjust enrichment claim.")
- North Carolina: *Baker Const. Co. v. City of Burlington*, No. COA09-13, 2009 WL 3350747, at *6 (N.C. Ct. App. Oct. 20, 2009) ("[T]his Court has limited the scope of a claim of unjust enrichment such that the benefit conferred must be conferred directly from plaintiff to defendant, not through a third party.")

- North Dakota: *Apache Corp. v. MDU Res. Group, Inc.*, 603 N.W.2d 891, 895 (N.D. 1999) (holding defendant's monetary savings "was not a 'benefit at the direct expense of'" plaintiff and thus failed to satisfy "the essential element of recovering under a theory of unjust enrichment")
- Ohio: *Bower v. Int'l Bus. Machs., Inc.*, 495 F. Supp. 2d 837, 844 (S.D. Ohio 2007) (putative class plaintiffs could not state a claim for unjust enrichment against manufacturer of hard drives where the consumers did not make a direct payment or confer a direct benefit on the manufacturer)
- Utah: *Concrete Prods. Co. v. Salt Lake Cnty.*, 734 P.2d 910, 911–12 (Utah 1987) ("We do not think that Salt Lake County was unjustly enriched No direct benefit, such as that demonstrated by the plaintiff in *Breitling*, is present here." (citing *Breitling Brothers v. Utah Golden Spikers, Inc.*, 597 P.2d 869 (Utah 1979)))

B. Examples Of States That Do Not Require A Benefit To Be Directly Conferred

- Illinois: *Muehlbauer v. General Motors Corp.*, 431 F. Supp. 2d 847, 853 (N.D. Ill. 2006) (Under Illinois law, "unjust enrichment claim may be premised on an indirect conferral of benefits.")
- Iowa: *State ex rel Palmer v. Unisys Corp.*, 637 N.W.2d 142, 155 (Iowa 2001) ("We have never limited [unjust enrichment] to require the benefits to be conferred directly by the plaintiff.")
- Maryland: *Bank of Am. Corp. v. Gibbons*, 918 A.2d 565, 571 (Md. Ct. Spec. App. 2007) ("[A] cause of action for unjust enrichment may lie against a transferee with whom the plaintiff had no contract, transaction, or dealing, either directly or indirectly.")
- Tennessee: *Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 525 (Tenn. 2005) ("[T]o recover for unjust enrichment, a plaintiff need not establish that the defendant received a direct benefit from the plaintiff.")

APPENDIX D:

STATES DIFFER AS TO THE TYPE OF CONDUCT NEEDED TO SUSTAIN A TORT-BASED UNJUST ENRICHMENT CLAIM

A. Examples Of States That Require Fraud Or Dishonesty

- Texas: *Heldenfels Bros. v. City of Corpus Christi*, 832 S.W.2d 39, 41 (Tex. 1992) (“A party may recover under the unjust enrichment theory when one person has obtained a benefit from another by fraud, duress, or the taking of an undue advantage”)
- Alabama: *Mantiplay v. Mantiplay*, 951 So.2d 638, 654-55 (Ala. 2006) (if unjust enrichment claim is not predicated upon mistake, plaintiff must prove “unconscionable conduct, such as fraud, coercion, or abuse of a confidential relationship”)
- Colorado: *DCB Const. Co. v. Central City Dev. Co.*, 965 P.2d 115, 117 (Colo. 1998) (“[F]or the enrichment to the landlord to be unjust and therefore actionable, the contractor must show some improper, deceitful, or misleading conduct by the landlord.”)
- Illinois: *Chatham v. Sears, Roebuck & Co. (In re Sears, Roebuck & Co. Tools Marketing & Sales Practices Litig.*, MDL No. 1703, Nos. 05 C 4742, 05 C 2623, 2007 WL 4287511, at *9 (N.D. Ill. Dec. 4, 2007) (holding that when unjust enrichment claim is predicated upon deceptive sales and marketing practices, “at least under Illinois law the[] unjust enrichment claims require proof of fraud” (citing 2006 WL 3754823, at *4 (N.D. Ill. Dec. 18, 2006)))

B. Examples Of States That Require Misconduct, But Something Less Than Fraud Or Dishonesty

- North Carolina: *Rhue v. Rhue*, 658 S.E.2d 52, 59 (N.C. App. Ct. 2008) (“Evidence of fraud is one way to establish an unjust enrichment claim but it may not be necessary. Evidence of fraud is unnecessary if the plaintiff establishes a ‘breach of duty’ or ‘some other circumstance making it inequitable’ for the defendant to retain his property interest.”)
- Virginia: *Qualichem v. Xelera, Inc.*, No. CL01-134, 2003 WL 23162331, at *3 (Va. Cir. Ct. June 19, 2003) (“claims of unjust enrichment based on quasi-contract have been limited by the appellate courts of the Commonwealth to those arising from: money paid by mistake; failed consideration; money got through imposition; extortion; oppression; or any other undue advantage taken of the claiming party’s situation, where the advantage is contrary to laws made for the protection of persons under those circumstances”)

C. Example Of States Where There Are Conflicting Conduct Requirements For An Unjust Enrichment Claim

- Minnesota: *Compare ServiceMaster v. GAB Bus. Servs., Inc.*, 544 N.W.2d 302, 306 (Minn. 1996) (requiring defendant be “unjustly enriched in the sense that the term ‘unjustly’ could mean illegally or unlawfully” (quoting *First Nat’l Bank v. Ramier*, 311 N.W.2d 502 (Minn. 1981))), with *Anderson v. DeLisle*, 352 N.W.2d 794, 796 (Minn. Ct. App. 1984) (“Fraud and mistake are not the only grounds for recovery under the theory of unjust enrichment. An action for unjust enrichment may be based on failure of consideration, fraud, mistake, and situations where it would be morally wrong for one party to enrich himself at the expense of another”)

D. Example Of States That Permit Unjust Enrichment Claims Against Parties Who Have Committed No Wrongdoing In Certain Circumstances

- Arkansas: *Smith v. Whitener*, 856 S.W.2d 328, 330 (Ark. App. Ct. 1993) (“Even an innocent party who has been unjustly enriched may be compelled to surrender the fruits to another more deserving party”).

APPENDIX E:

STATES DIFFER AS TO THE STATUTE OF LIMITATIONS FOR UNJUST ENRICHMENT CLAIMS

A. Examples Of States With A 3-Year Limitation Period For Unjust Enrichment Claims

- Arizona: *Frew v. Coit Servs.*, No. CV-07-1372-PHX-DGC, 2007 WL 2903026, at *2 (D. Ariz. Oct. 2, 2007) (a three-year limitation period applies to fraud and unjust enrichment claims (citing A.R. S. § 12-543))
- Colorado: *Luttgen v. Fischer*, 107 P.3d 1152, 1157 (Colo. App. 2005) (“A three-year limitations period applies to claims for unjust enrichment.” (citing § 13–80–101(1)(a), C.R.S.2004; *Rotenberg v. Richards*, 899 P.2d 365, 368 (Colo. App. 1995)))
- Delaware: *Shandler v. DLJ Merch. Banking, Inc.*, C.A. No. 4797-VCS, 2010 WL 2929654, at *9 n.88 (Del. Ch. July 26, 2010) (“Under Delaware law, claims for breach of fiduciary duty, professional malpractice, and unjust enrichment are covered by a three year statute of limitations.” (citing 10 Del. C. § 8106))
- Maryland: *Baltimore City Bd. of School Comm’rs v. Koba Inst., Inc.*, 5 A.3d 60, 72 (Md. Ct. Spec. App. 2010) (“[T]he three-year period set forth in CJP § 5–101 would control an unjust enrichment claim.”)
- North Carolina: *Housecalls Home Health Care, Inc. v. N.C. Dep’t of Health & Human Servs.*, 682 S.E.2d 741, 744 (N.C. Ct. App. 2009) (“Under our General Statutes, the statute of limitations for bringing a cause of action for breach of contract, conversion, or unjust enrichment is three years.” (citing N.C. Gen. Stat. § 1–52(1), (4) (2007)))
- Virginia: *Primrose Dev. Corp. v. Benchmark Acq’n Fund I, L.P.*, No. 19161, 47 Va. Cir. 296, 1998 WL 957312, at *2 (Va. Cir. Ct. Oct. 29, 1998) (“[n]either side disputes that the Plaintiff’s claim for unjust enrichment, although a claim in equity, is subject to the statute of limitations; nor that pursuant to Virginia Code § 8.01-246(4) the statute of limitations that is to be applied is three years.” (citations omitted))
- Washington: *Seattle Prof’l Eng’g Emps. Ass’n v. Boeing Co.*, 991 P.2d 1126, 1133 (Wash. 2000) (“Washington case law has applied a three-year statute of limitations to claims involving unjust enrichment.” (citing RCW 4.16.080 (3)))
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B. Examples Of States With A 4-Year Limitation Period For Unjust Enrichment Claims

- Florida: *Brown v. Nationscredit Fin. Servs.*, 32 So. 3d 661, 662 n.1 (Fla. 1st DCA 2010) (“Appellants’ claim for unjust enrichment is also subject to a four-year statute of limitations pursuant to section 95.11(3)(k).”)
- Pennsylvania: *Sevast v. Kakouras*, 915 A.2d 1147, 1153 (Pa. 2007) (“The cause of action which Appellee brought before the court is based upon a theory of unjust enrichment. According to statute, there is a four-year statute of limitations for such causes of action.” (citing 42 Pa. C.S. § 5525(a)(4)))

C. Example Of States With A 5-Year Limitation Period For Unjust Enrichment Claims

- Illinois: *Lewandowski v. Jelenski*, 929 N.E.2d 114, 119 (Ill. App. Ct. 2010) (A “cause of action for unjust enrichment is subject to the five-year statute of limitations as set forth by section 13–205.” (citing *Frederickson v. Blumenthal*, 648 N.E.2d 1060 (Ill. App. Ct. 1995)))

D. Example Of States With A 6-Year Limitation Period For Unjust Enrichment Claims

- Connecticut: *Corbett v. Petrillo*, No. CV065005440S, 2008 WL 726373, at *4 (Conn. Super. Ct. Feb. 29, 2008) (“As to the claims of unjust enrichment, there is no Connecticut appellate authority that squarely addresses which is the appropriate statute of limitations. ‘A cause of action for unjust enrichment is generally viewed as sounding in quasi-contract, and the statute of limitations for unjust enrichment is generally held to be six years’ Thus, at a minimum, the time limitation for claims of unjust enrichment is six years.” (internal citations omitted))
- Minnesota: *Block v. Litchy*, 428 N.W.2d 850, 854 (Minn. Ct. App. 1988) (“The applicable time limit for bringing an action in unjust enrichment is six years.” (citing Minn. Stat. § 541.05, subd. 1(1) (1986)))
- New York: *37 Park Drive S., Inc. v. Duffy*, 881 N.Y.S.2d 481, 482, 63 A.D.3d 1040, 1041 (N.Y. App. Div. 2009) (“[T]he plaintiff was entitled to recover [] based upon a theory of an implied contract or unjust enrichment, which carries a six-year statute of limitations.”)

APPENDIX F:

STATES DIFFER AS TO THE RULES REGARDING WHEN THE STATUTE OF LIMITATIONS STARTS TO ACCRUE

A. Examples Of States Where Unjust Enrichment Claim Accrues When The Plaintiff Knows Or Reasonably Should Know Of The Unjust Enrichment

- Arizona: *Stratton v. Am. Med. Sec., Inc.*, No. CV-07-1491-PHX-SMM, 2008 WL 2039313, at *3 (D. Ariz. May 12, 2008) (“Under Arizona’s discovery rule, a plaintiff’s cause of action does not accrue until the plaintiff knows or, in the exercise of reasonable diligence, should know the facts underlying the cause.” (quoting *Gust, Rosenfeld & Henderson v. Prudential Ins. Co. of Am.*, 898 P.2d 964, 966 (Ariz. 1995)))
- Colorado: *Sterenbuch v. Goss*, 266 P.3d 428, 437 (Colo. App. 2011) (“A claim of unjust enrichment accrues ‘when a person discovers, or through the exercise of reasonable diligence should discover, that all elements of the claim are present.’” (internal citations omitted))
- Illinois: *Wetherell v. ClimateMaster, Inc.*, No. 07-CV-0696-MJR, 2009 WL 4043539, at *3 (S.D. Ill. Nov. 20, 2009) (statute of limitations for unjust enrichment claim under Illinois law “starts running ‘when a person knows or reasonably should know of his injury and also knows or reasonably should know that it was wrongfully caused’” (internal citations omitted))
- Maryland: *Ver Brycke v. Ver Brycke*, 843 A.2d 758, 775 (Md. 2004) (claim for unjust enrichment starts to accrue “when the ‘plaintiff discovers, or through the exercise of due diligence, should have discovered, the injury.’” (internal citations omitted))

B. Examples Of States Where Unjust Enrichment Claim Accrues When The Wrongful Act Occurs

- Delaware: *Winner Acceptance Corp. v. Return on Capital Corp.*, Civil Action No. 3088–VCP, 2008 WL 5352063, at *14 (Del. Ch. Dec. 23, 2008) (unjust enrichment “cause of action . . . accrues at the time of the wrongful act, even if the plaintiff is ignorant of the cause of action”)
- New York: *Congregation Yetev Lev D’Satmar, Inc. v. 26 Adar N.B. Corp.*, 192 A.D.2d 501, 503 (N.Y. App. Div. 1993) (“The plaintiffs’ causes of action to recover damages for unjust enrichment and to impose a constructive trust are barred by the six-year Statute of Limitations found in CPLR 213(1), which starts to run upon the occurrence of the wrongful act giving rise to a duty of restitution”)

C. Examples Of States Where Unjust Enrichment Claim Accrues When The Benefit Is Conferred By The Plaintiff And Accepted By The Defendant

- Florida: *Merle Wood & Assocs. v. Trinity Yachts, LLC*, No. 10–61997–CIV, 2011 WL 845825, at *6 (S.D. Fla. Mar. 7, 2011) (holding under Florida law that “quantum meruit and unjust enrichment claims accrue at the time the alleged benefit is conferred by the plaintiff on the defendant and the defendant accepts such benefit”)
- Virginia: *GIV, LLC v. Int’l Bus. Machines Corp.*, Civil Action No. 3:07CV067-HEH, 2007 WL 1231443, at *2 (E.D. Va. Apr. 24, 2007) (“An unjust enrichment action accrues when the unjust enrichment actually occurs, i.e., when the expected compensation is not paid, not when a party knew or should have known of the unjust enrichment”)
- Pennsylvania: *Harry Miller Corp. v. Mancuso Chems. Ltd.*, 469 F. Supp. 2d 303, 319 (E.D. Pa. 2007) (“A claim for unjust enrichment accrues when the defendant ‘receives and retains benefits’” (quoting *Konidaris v. Portnoff Law Associates, Ltd.*, 884 A.2d 348, 355 (Pa. Cmwlth. 2005)))

D. Example Of States Where Unjust Enrichment Claim Accrues When Plaintiff Has The Right To Apply For Relief

- Washington: *Lowden v. T-Mobile USA, Inc.*, 2009 WL 537787, at *4 (W.D. Wash. Feb. 18, 2009) (“The statute of limitations on a claim for unjust enrichment begins to run when the party has ‘the right to apply for relief.’ (quoting *Eckert v. Skagit Corp.*, 583 P.2d 1239 (Wash. App. Ct. 1978)), *aff’d sub nom. Lowden v. T-Mobile USA Inc.*, 378 F. App’x 693 (9th Cir. 2010))

APPENDIX G:

STATES DIFFER AS TO WHETHER UNJUST ENRICHMENT CLAIMS CAN SURVIVE WHEN THERE IS AN ADEQUATE REMEDY AT LAW

A. Examples Of States That Preclude Unjust Enrichment Claims When The Plaintiff Has An Adequate Remedy At Law

- Arizona: *Cnty. Guardian Bank v. Hamlin*, 898 P.2d 1005, 1008 (Ariz. Ct. App. 1995) (“In Arizona, five elements must be proved to make a case of unjust enrichment [including] . . . an absence of a remedy provided by law.”)
- Hawaii: *Porter v. Hu*, 169 P.3d 994, 1007 (Haw. App. 2007) (“As to the question of when an equitable remedy may be invoked, this court observes the principle, long-invoked in the federal courts, that equity has always acted only when legal remedies were inadequate.” (quotations omitted))
- Missouri: *Bennett v. Crane*, 289 S.W. 26, 28 (Mo. 1926) (recognizing that a claim in equity requires “the inadequacy of the remedy at law.”)
- New York: *Featherstonhaugh v. Roemer*, 279 A.D.2d 783 (N.Y. App. Div. 2001) (unjust enrichment claim fails if “plaintiffs have an adequate remedy at law”)
- Pennsylvania: *Fish Net, Inc. v. ProfitCenter Software, Inc.*, 2011 WL 1235204, at *9 (E.D. Pa. March 31, 2011) (“An unjust enrichment claim is subject to the ‘basic tenet of equity jurisprudence’ that ‘if an adequate remedy at law exists, equitable relief will not be granted.’” (internal citations omitted))
- Colorado: *Harris Group, Inc. v. Robinson*, 209 P.3d 1188, 1207 (Colo. Ct. App. 2009) (holding “that the company had an adequate remedy at law, and that all of the jury awards for unjust enrichment must therefore be reversed.”)

B. Examples Of States That Permit Unjust Enrichment Claims, At Least In Some Circumstances, Even When The Plaintiff Has An Adequate Remedy At Law

- Arkansas: *Thomas v. Bayer Corp.*, No. 4:07CV00017 JMM, 2009 362982, at *6 (E.D. Ark. Feb. 12, 2009) (Arkansas does not have requirement that there be no adequate remedy at law to bring unjust enrichment claim)
- Illinois: *Indep. Voters of Illinois v. Illinois Commerce Com’n*, 117 Ill. 2d 90, 96 (Ill. 1987) (holding that restitution predicated on unjust enrichment “usually” requires that no adequate legal remedy exist)
- Oklahoma: *Harvell v. Goodyear Tire & Rubber Co.*, 164 P.3d 1028, 1035 (Okla. 2006) (noting that “[w]here the plaintiff has an adequate remedy at law, the court will not *ordinarily* exercise its equitable jurisdiction to grant relief for unjust enrichment.” (emphasis added))

C. Examples Of States That Are Divided As To Whether There Is An Adequate Remedy Of Law Requirement For Unjust Enrichment Claims

- Florida: Compare *Williams v. Bear Stearns & Co.*, 725 So. 2d 397, 400 (Fla. 5th DCA 1998) (“Although Appellees argue that Appellant has adequate legal remedies and therefore no equitable relief can be granted, this notion does not apply to unjust enrichment claims”), with *Matthews v. Am. Honda Motor Co., Inc.*, 2012 WL 2520675, at *2 (S.D.Fla. June 6, 2012) (holding that under Florida law, “unjust enrichment is an equitable remedy that is available only when the plaintiff lacks an adequate remedy at law” and that “because Matthews’ unjust enrichment claim is predicated on the same wrongful conduct as her FDUTPA claim, she does not lack an adequate legal remedy”)

APPENDIX H:

STATES DIFFER AS TO THE AVAILABILITY AND DEFINITION OF CERTAIN AFFIRMATIVE DEFENSES

A. Examples Of Stats Which Permit The Defense Of Laches To Unjust Enrichment Claims

- Connecticut: *Crown Linen Serv., Inc. v. CT Appliance & Fireplace Distrib., LLC*, No. HHDCV075011439S, 2009 WL 765531, at *5 (Conn. Super. Ct. Feb. 24, 2009) (“In the second count of the complaint, the plaintiff seeks to recover on the equitable theory of unjust enrichment. As such, the defendant appropriately asserts the equitable defense of laches.”)

B. Examples Of States Which Do Not Permit The Defense Of Laches To Unjust Enrichment Claims

- Illinois: *Partipilo v. Hallman*, 510 N.E.2d 8, 12 (Ill. App. Ct. 1987) (prohibiting application of laches to unjust enrichment claim under Illinois law)

APPENDIX I:

STATES DIFFER REGARDING WHAT COSTS CAN BE DEDUCTED WHEN PERFORMING A DISGORGEMENT OR ANALOGOUS “LOST PROFIT” ANALYSIS

A. Examples Of States That Require Fixed Costs To Be Deducted

- Pennsylvania: *Aiken Indus., Inc. v. Estate of Wilson*, 383 A.2d 808, 813 n.7 (Pa. 1978) (Court vacated damages award for breach of contract in part because lower court’s calculation of lost profits “established only that percentage of total sales income remaining after deduction of variable costs. To establish a net profit, it is necessary also to deduct other fixed costs.”)
- Texas: *Adkins Adjustment Servs., Inc. v. Neal*, 05-00-01419-CV, 2001 WL 1231685, at *1-2 (Tex. App. Oct. 17, 2001) (affirming grant of direct verdict in favor of defendant on plaintiff’s business tort claims because plaintiff’s expert only deducted direct variable costs in determining plaintiff’s lost profits and failed to account for “nonallocable expenses, such as rent, officer salaries, general clerical salaries, general insurance payments, or utility charges”)
- Virginia: *SI Int’l Tech. Servs., Inc. v. Nat’l Techs. Assocs., Inc.*, No. 2005-3131, 73 Va. Cir. 3, 2006 WL 2844424 (Va. Cir. Ct. Sept. 18, 2006) (finding that Virginia law does not differentiate between fixed costs and variable costs and recognizing that the Virginia Supreme Court has included “fixed charges” as an appropriate cost to be deducted from gross revenue to determine lost profit (citing *Worrell & Williams v. Kinnear Mfg. Co.*, 49 S.E. 988 (Va. 1905)))

B. Examples Of States That Do Not Permit Indirect Fixed Costs To Be Deducted

- Illinois: *F.E. Holmes & Son Const. Co. v. Gualdoni Elec. Serv., Inc.*, 435 N.E.2d 724, 728 (Ill. App. Ct. 1982) (“Net lost profits are determined by subtracting the expenses necessary for plaintiff’s full performance from the contract price because these expenses are generally avoided by the defendant’s breach. Plaintiff’s cost of performance is comprised of direct costs (labor and materials) and indirect costs (overhead). The direct costs and that portion of indirect costs which can be avoided by defendant’s breach, called variable indirect costs, are deducted from the contract price. In contrast, that portion of indirect costs which cannot be reduced by defendant’s breach, called fixed indirect costs, are not subtracted from the contract price.”)
- Maryland: *David Sloane, Inc. v. Stanley G. House & Assocs.* 532 A.2d 694, 701 (Md. 1987) (“In our view the cases holding that reasonable, fixed expenses need not be deducted from gross income to arrive at lost profit properly recoverable are more persuasive.”)